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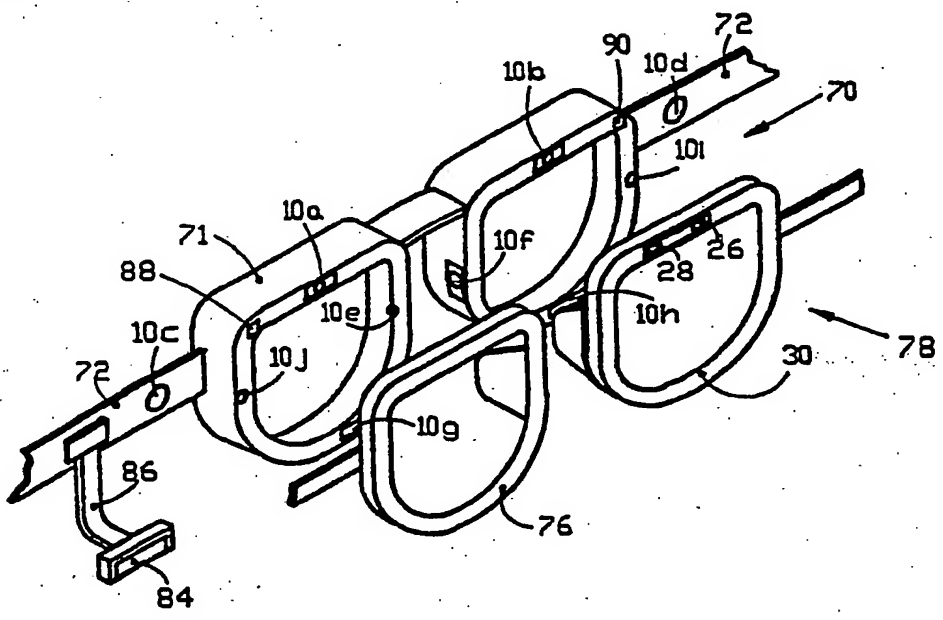

(57) Abstract

Apparatus for mounting electrodes (10) on a human body in order to obtain human biosignals is disclosed. The apparatus includes close fitting clothing apparatus (70), a plurality of electrodes (10) mounted to the close fitting clothing apparatus (70), removable cover sheet apparatus (78) for providing a sterile interface between the skin and at least one of the electrodes (10) and joining apparatus for joining the removable cover sheet apparatus (78) to at least one of the plurality of electrodes (10). A variety of applications of the apparatus are also disclosed, including apparatus (130) for detecting drowsiness in a subject and for alerting the subject as a result and a fetal biosignal probe (200).

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APPARATUS FOR MOUNTING ELECTRODES

FIELD OF THE INVENTION

The present invention relates generally to apparatus for the rapid placement of electrodes on and acquisition of signals from the human body.

BACKGROUND OF THE INVENTION

Many medical tests require the acquisition of bioelectric signals from the brain, eyes, muscles or nerves or from a combination of the abovementioned body parts. Other biosignals, such as electrodermal signals, heart pulse, voice signals, etc., are often also required.

U.S. Patent 3,882,846 describes a capacitive electrode for acquiring electrocardiographic (ECG) signals which does not necessitate the use of conductive gels or the preparation of the skin of a subject before acquiring the ECG signals. While a major improvement in the practicality of ECG signal acquisition, the capacitive electrode still requires use of a conventional conductive electrode as a reference ground. In addition, there is no convenient way to sterilize the capacitive electrode between patients.

Furthermore, when pairs of the capacitive electrodes are utilized to obtain differential voltage measurements of bioelectric signals, the robustness of the signal acquisition in the face of various movement-related artifacts is low. Noise pickup from extraneous electromagnetic sources due to cabling is substantial.

It is known in the art that preparing the skin

and the electrodes, placing the electrodes in their correct location on the body, and fastening them to the body is a time-consuming process requiring much skill. Many devices have been created to ensure correct placement of the electrodes on the body.

One such device is described in U.S. Patent 4,800,888. It comprises a helmet onto which is mounted an electrode assembly. Each electrode of the assembly floats in a cylinder which is mounted on a pressure responsive drive. When the pressure responsive drive is under pressure, it carries the electrode to the scalp of a subject.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide an apparatus for mounting electrodes on the human body and for acquiring bioelectric signals therefrom without skin preparation and with minimal expertise.

It is also an object of the present invention to provide practical means for sterile use of capacitive electrodes.

There is therefore provided, in accordance with a preferred embodiment of the present invention, apparatus for mounting electrodes on a human body which apparatus is operative to obtain human biosignals and comprises close fitting clothing apparatus, a plurality of electrodes mounted to the close fitting clothing apparatus, removable cover sheet apparatus for providing a sterile interface between the skin and at least one of the electrodes and joining apparatus for joining the cover sheet apparatus to at least one of the plurality of electrodes.

Additionally, in accordance with a preferred embodiment of the present invention, the apparatus for mounting electrodes on a human body also comprises signal processing apparatus mounted on the close fitting clothing apparatus for preamplifying, transient

protecting and filtering at least one differential signal obtained between two of the electrodes.

Moreover, in accordance with a preferred embodiment of the present invention, the cover sheet apparatus includes reference apparatus for providing a reference signal for at least one of the plurality of electrodes. Alternatively, the cover sheet apparatus includes conductive apparatus for providing a conductive path between at least one of the plurality of electrodes and the human body.

Still further, in accordance with a preferred embodiment of the present invention, at least one of the plurality of electrodes is a capacitive electrode.

Additionally, in accordance with a preferred embodiment of the present invention, the close fitting clothing apparatus can be a glove, a face mask, goggles, a headband, glasses, a cap or a pilot flight helmet. If the close fitting apparatus is a glove, a photoplethysmographic sensor may be included.

There is also provided, in accordance with an embodiment of the present invention, a referenced capacitive electrode assembly for mounting on human skin comprising a capacitive electrode mounted in a substrate, sterilizable removable cover apparatus separate from the capacitive electrode for providing an electrical reference signal and for providing a separable interface between the human skin and at least one of the electrodes and joining apparatus for joining the cover apparatus to the capacitive electrode.

There is additionally provided, in accordance with an embodiment of the present invention, a referenced capacitive sensor channel assembly for mounting on human skin for the purpose of measuring bioelectric signals. The sensor channel comprises a set of at least two capacitive electrodes mounted in a substrate, removable cover apparatus separate from the set of capacitive electrodes for providing a separable

interface between the human skin and at least one of the capacitive electrodes and including reference apparatus for providing an electrical reference signal for the sensor channel, joining apparatus for joining the cover apparatus to the capacitive electrodes and signal processing apparatus for processing the bioelectric signals.

Furthermore, there is provided, in accordance with an embodiment of the present invention, a capacitive electrode for mounting on human skin and comprising a housing having a skin-facing side in which there is an opening, a conductive element placed in the opening and lying along the skin-facing side, and a dielectric cover covering the opening and touching the conductive element.

There is further provided, in accordance with a preferred embodiment of the present invention, apparatus for alerting a drowsing subject comprising a close fitting frame mounted on the subject's head, a plurality of electrodes mounted to the close fitting frame for measuring biosignal activity occurring generally in the area of the face and head of the subject, data processing apparatus for processing the biosignal activity into baseline curves and for determining when the biosignal activity crosses a threshold related to the baseline curves for longer than a predetermined amount of time indicating an increased risk of drowsiness, and alerting apparatus for alerting the drowsing subject upon determination by the data processing apparatus that an increased risk of drowsiness has occurred.

Additionally, in accordance with a preferred embodiment of the invention, the biosignals can be of high and/or low frequency and the apparatus includes response detection means for detecting the subject's response to an alert issued by the alerting apparatus.

Moreover, in accordance with a preferred

embodiment of the present invention, the alerting apparatus includes apparatus for producing a variety of audible sounds. The alerting apparatus also includes apparatus for varying the intensity of the audible sounds.

Further, in accordance with a preferred embodiment of the present invention, a head motion sensor for detecting head motion is also optionally included in the apparatus for alerting a drowsing subject.

Still further, in accordance with an embodiment of the present invention, the close fitting frame is a frame of a pair of eyeglasses, a set of goggles, a headband or a frame of a face mask.

There is further provided, in accordance with an embodiment of the present invention, a method of alerting a drowsing subject including the steps of receiving biosignals from electrodes placed on and near the face of the subject, processing the biosignals into baseline curves, and determining when amplitudes of the biosignals cross the baseline curves for longer than a predetermined amount of time indicating an increased risk of drowsiness, alerting the subject via an alerting action every time the increased risk of drowsiness is indicated, and detecting a response to the alerting action.

Further, in accordance with an embodiment of the present invention, the alerting action differs each time the increased risk of drowsiness is indicated. The alerting action is an audible sound whose intensity is initially low and intensifies until the subject gives a confirmatory response indicating that the subject is alert.

There is further provided, in accordance with an embodiment of the present invention, apparatus for rapidly preparing to obtain biosignals from a human body and comprising close fitting clothing apparatus, a

plurality of electrodes mounted to the close fitting clothing apparatus, wherein at least one of the electrodes is a capacitive electrode and reference apparatus mounted to the close fitting clothing apparatus for providing a reference signal for use together with the at least one capacitive electrode.

Moreover, there is provided, in accordance with an embodiment of the present invention, eye tracking apparatus for tracking the direction of a subject's gaze comprising, close fitting clothing apparatus mounted close to the face of the subject, at least first and second pairs of capacitive electrodes for obtaining biosignals relating to the gaze mounted onto the close fitting clothing apparatus, wherein the first pair is mounted so as to be above and below one of the subject's eyes and wherein the second pair is mounted so as to be on opposite sides of one of the subject's eyes, and apparatus for converting the biosignals into position information.

Additionally, there is provided, in accordance with an embodiment of the present invention, a fetal biosignal probe for rapidly obtaining biosignals of a fetus, typically during labor, comprising at least one capacitive electrode apparatus mounted on a flexible body for obtaining fetal biosignals and referencing apparatus for providing a reference signal for the capacitive electrode apparatus.

Furthermore, in accordance with an embodiment of the present invention, there is provided a system for rapidly obtaining fetal biosignals comprising at least two fetal biosignal probes to be temporarily attached to a fetus scalp and signal processing apparatus for processing fetal electroencephalographic signals.

Finally, there is provided in accordance with an embodiment of the present invention, apparatus and a method for measuring a critical flicker fusion frequency of a subject and comprising a plurality of light sources

arranged in a predetermined pattern, typically familiar to a subject, comprising a first multiplicity of background light sources and a second multiplicity of flicker group light sources, driving circuitry apparatus for illuminating the background light sources so as to appear non-flickering, for oscillating the flicker group light sources at a gradually decreasing oscillation frequency and for maintaining the background and flicker group light sources visually indistinguishable, and input apparatus operated by the subject for indicating to the driving circuitry apparatus at which frequency flicker is first observed in the flicker group and which of the plurality of light sources belongs to the flicker group.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1A is an isometric illustration of an electrode assembly and a cover sheet assembly covering the electrode assembly constructed and operative in accordance with an embodiment of the present invention;

Fig. 1B is a side view sectional illustration of the electrode and cover sheet assemblies of Fig. 1A;

Figs. 1C and 1D are side view sectional illustrations of alternative embodiments of the electrode of Fig. 1A;

Fig. 2 is a side view sectional illustration of an electrode assembly and an alternative embodiment of the cover sheet assembly of Fig. 1B useful for incorporating conductive lubrication means;

Fig. 3A is a schematic illustration of a face mask having any one of the electrode assemblies of Fig. 1 and two sterile integrated electrode covers constructed and operative in accordance with an embodiment of the present invention;

Fig. 3B is a detailed schematic illustration of one of the sterile integrated electrode covers of Fig. 3A;

Fig. 4 is a schematic illustration of an alternate embodiment of the face mask of Fig. 3 in conjunction with a flexible printed circuit;

Fig. 5 is a detailed schematic illustration of the flexible printed circuit of Fig. 4;

Fig. 6 is an electronic schematic diagram of a circuit for preamplification, transient protection and filtering of bioelectric signals;

Fig. 7A is a pictorial illustration of a cap in which are incorporated the electrode assemblies of Fig. 2;

Figs. 7B and 7C are pictorial illustrations of a pilot flight helmet into which are incorporated capacitive electrodes;

Fig. 8 is a pictorial illustration of a glove in which are incorporated any one of the electrode assemblies of Fig. 1;

Figs. 9A, 9B and 9C are pictorial illustrations of an apparatus for detecting drowsiness of a subject and for subsequently alerting said subject;

Figs. 10A and 10B are graphic illustrations of RMS amplitude curves of low and high frequency signals produced by the apparatus of Figs. 9A - 9C;

Fig. 11 is a block diagram illustration of processing apparatus useful in the apparatus of Figs. 9A - 9C;

Fig. 12 is a schematic circuit diagram of a signal conditioning module useful in the processing means of Fig. 11;

Fig. 13 is a schematic illustration of flexible circuit board apparatus useful in the apparatus of Figs. 9A - 9C;

Figs. 14A, 14B and 14C are front, back and side view illustrations of a fetal biosignal probe

utilizing the electrodes of Fig. 1;

Figs. 15A, 15B and 15C are front, back and side view illustrations of an alternative embodiment of a fetal biosignal probe utilizing the electrodes of Fig. 1;

Fig. 16 is a part pictorial, part block diagram illustration of a system for obtaining fetal biosignals during delivery using one or both of the fetal biosignal probe of Figs. 14 and 15;

Fig. 17 is a part pictorial, part block diagram illustration of apparatus for measuring Critical Flicker Fusion; and

Fig. 18 is an electronic schematic of circuitry forming part of the apparatus of Fig. 17.

DETAILED DESCRIPTION OF PRESENT INVENTION

Reference is now made to Figs. 1A and 1B which illustrate an electrode assembly 10 and a cover sheet assembly 12. Electrode assembly 10 typically comprises a capacitive electrode 14, such as those available from Heart Rate Inc. of Costa Mesa, Ca.

Electrode assembly 10 additionally comprises a flexible non-conducting substrate 16, such as silicone rubber or soft plastic, in which is mounted capacitive electrode 14. Also mounted in substrate 16, near electrode 14, is at least one electrical contact site, shown in Fig. 1B as two contact sites 18 and 20.

Attached to electrical contact sites 18 and 20 and to electrode 14, and passing through or residing within substrate 16, are electrical conductors 22. Electrical conductors 22 terminate at an electrical connector 24.

Cover sheet assembly 12 is typically a thin sheet which is typically disposable but may alternatively be permanent. It typically comprises at least one electrical contact medium, shown in Fig. 1B as contact media 26 and 28, for touching human skin and for providing an electrical reference signal to electrode

14. Media 26 and 28 are typically conductive silver impregnated cloth electrodes, such as the E301 or E331 electrodes manufactured by In-Vivo Metric of Healdsburg, Ca., and are typically mounted on a non-conductive substrate 30, such as a thin plastic sheet. Through openings in substrate 30, media 26 and 28 are electrically connected to metallic contacts 32 and 34. The metallic contacts 32 and 34 are designed to easily and removably attach but firmly to contact sites 18 and 20, thereby providing a reference signal for electrode 14. In the preferred embodiment shown hereinabove, a pair of one contact site 18 or 20 and one metallic contact 32 or 34 creates both a mechanical and an electrical connection between the cover sheet assembly 12 and the electrode assembly 10. An appropriate pair is a male-female press contact pair such as the Dot contact manufactured by TRW Corporation of the USA. Alternatively, the pair can be formed of silver impregnated cloth fasteners formed of Velcro (registered trademark).

In an alternate embodiment, the mechanical joining and the electrical joining can be produced separately by two separate connection assemblies. An example of such a dual joining assembly is an adhesive band around the border of cover 12 on the side of substrate 30 which is not in contact with the skin for mechanical joining and a separate Dot contact pair inside the border for electrical joining.

An alternate embodiment of electrode assembly, labeled 40, is shown in Fig. 2 and is intended for use, in conjunction with a cover sheet assembly 42, on areas covered by body hair. Cover sheet assembly 42 comprises a substrate 44, preferably made of a thin plastic film, and a multiplicity of sponges 46 filled with a moist conductive gel or similar conductive medium and attached to the substrate 44. A protective, sealing cover film 48, such as is used in commercial disposable ECG

electrodes such as the Red Dot electrode manufactured by 3M Corporation of Minnesota, USA, maintains the gel in sponge 46 in a wetted state and is typically peeled from the cover 42 after the cover 42 is attached to electrode 14.

As in cover sheet assembly 12, cover sheet assembly 42 additionally comprises contact media 26 and 28 and metallic contacts 32 and 34 for providing a reference signal for electrode 14.

Similar to electrode assembly 10, electrode assembly 40 comprises a substrate 50, similar to flexible substrate 16, in which are mounted electrode 14, contacts 18 and 20 and any necessary wires. Cover sheet assembly 42 is attached to substrate 50 via adhesive pads 52 such that sponges 46 lie on top of electrode 14 and media 26 and 28. Alternatively, adhesive pads 52 can be made of Velcro (registered trademark).

It will be appreciated that sponge 46 provides a moist electrical connection between the skin and substrate 44. Substrate 44 may optionally have pores under sponge 46 to establish electrical contact with electrode 14 and media 26 and 28. The sealing cover film 48 is made to hermetically seal off all sides of cover 42 so as to preserve the moistness of sponges 46. Sealing cover film 48 is similar to those used for disposable ECG electrodes.

It will further be appreciated that the electrode apparatus 10 or 40 is first covered by its respective cover sheet assembly 12 or 42 and then the combination is placed onto the skin of a subject, with the cover assembly side located against the skin. Via the electrode and cover sheet assembly combination, reference and bioelectric signals are gathered, without the necessity of skin preparation. Due to the replaceability of cover assemblies 12 and 42, electrode assemblies 10 and 40 are hygienic and suitable for

sterile use with a multiplicity of subjects.

Reference is now made to Figs. 1C and 1D which illustrate alternative embodiments of electrode assembly 40 in which a single dielectric layer separates the skin from the conductive element of the capacitive electrode 14.

In accordance with this embodiment of the present invention, the capacitive electrode, here denoted 60, comprises a conductive element 62, such as a piece of metal, a dielectric material 64, such as a thin plastic sheet, forming a cover to a three-sided housing 66, and a buffer amplifier 68.

Capacitive electrode 60 performs as a capacitor after being mounted, dielectric material 64 side down, onto the human skin. Buffer amplifier 68 operates in a manner similar to the buffer amplifier in U.S. Patent 3,882,846. It is operative on the signal detected by the combination of the conductive element 62 and the dielectric material 64.

The conductive element 62 and the buffer amplifier 68 are enclosed within housing 66 which is covered by dielectric material 64. Conductive element 62 is placed inside housing 66 in a location close to the side of housing 66 which is covered by dielectric material 64. In this manner, conductive element 62 touches dielectric material 64. The dielectric material 64 can be formed as an integral part of housing 66, as shown in Fig. 1C, or as a detachable element, as shown in Fig. 1D. In the embodiment of Fig. 1D, the dielectric material 64 operates both as a dielectric and as the substrate of cover sheet assembly 12 of Fig. 1B.

It will be appreciated that the capacitive electrodes 60 of Figs. 1C and 1D can be utilized in place of capacitive electrode 14 in the assembly of Fig. 1B. Capacitive electrode 60 is advantageous over capacitive electrode 14 in that capacitive electrode 14 typically has two dielectric layers, one inside the

electrode housing and one defining substrate 30, while capacitive electrode 60 has only one dielectric layer 64 which serves both as a dielectric and as a cover sheet assembly.

Reference is now made to Figs. 3A, 3B, 4 and 5 which illustrate apparatus 70, constructed and operative in accordance with a preferred embodiment of the present invention, for rapidly applying electrodes, such as any of the electrodes of Fig. 1, to the face of a subject. Apparatus 70 requires no skin or electrode preparation, nor does it require much knowledge on the part of the operator as to the correct placement of the electrodes. It is designed to be easy for an unskilled operator to use and to be comfortable and hygienic for a subject to wear.

Accordingly, apparatus 68 is typically embodied in a face mask 70, including a pair of frames 71, similar to the frames of swimmer's goggles and typically manufactured of a soft material such as silicone rubber or a soft plastic, an adjustable bridge 72 for enabling the face mask 70 to adapt to the particular interocular distance of a subject and an adjustable band 74, typically an elastic band, for firmly maintaining the face mask 70 against the face of a subject. The adjustability of the adjustable band 74 accommodates subjects with different head sizes.

Mounted onto face mask 70 are a multiplicity of electrode assemblies, such as apparatus 10 (Figs. 1A and 1B), labeled 10a - 10j, for receiving facial biosignals. The electrode assemblies 10a - 10j are located in predetermined locations around the eyes so as to measure biosignals relating to eye movement and eye position. Specifically, electrodes 10a and 10b are located in frame 71 so as to be above a subject's pupils and electrodes 10g and 10h are arranged so as to be located below the subject's pupils. Electrodes 10e and 10f are located so as to be placed in the inner canthus

of the eyes and electrodes 10j and 10i are located so as to be placed in the outer canthi of the eyes. Electrodes 10c and 10d are arranged to be located at the temples and are therefore placed on adjustable band 72.

Typical biosignals to be measured are as follows: electrode pairs 10a and 10g and 10b and 10h measure electrooculograms (EOGs) relating to the vertical motion and position of the left and right eyes, respectively, and electrode pairs 10j and 10e and 10f and 10i measure EOGs relating to the horizontal motion and position of the left and right eyes, respectively. Alternatively, electrodes 10e and 10f may be replaced by a single electrode at 10e, at 10f, on the nose bridge, or between the eyebrows. The horizontal and vertical motion measurements are useful for detecting nystagmus and for measuring a subject's blink response and the convergence capability of a subject's eyes.

Electrodes 10a and 10b, located above the pupils, are also useful for measuring the electromyogram (EMG) of facial muscles and electrodes 10c and 10d are useful for measuring EMGs of muscles associated with eye lids and eye movements or with facial relaxation.

In accordance with a preferred embodiment of the present invention, the cover sheet assemblies 12 corresponding to the multiplicity of electrodes 10a - 10j are formed in two integrated cover sheet assemblies 76 and 78. Covers 76 and 78 are designed so as to cover all of the portions of face mask 70 which come into contact with the skin of a subject, including the temples and the areas near the inner canthi of the eyes. They are replaceable so as to ensure that apparatus 70 is hygienic and can be used with a multiplicity of subjects without concern of spreading disease from one subject to the next.

Cover sheet assembly 78 is shown in detail in Fig. 3B and cover sheet assemblies 76 and 78 are both shown in Fig. 4. Cover sheet assembly 78 includes

substrate 30 onto which are placed one or more media 26 and 28, where, for clarity's sake, only one pair of media 26 and 28 are shown. Media 26 and 28 are arranged on substrate 30 such that they will mate with the corresponding electrode assembly 10 located on face mask 70.

The entirety of electrode assemblies 10 are connected to signal processing equipment via electrical connections 80 (Fig. 5), typically comprised of wires. In accordance with a preferred embodiment of the present invention, electrode assemblies 10 and their respective electrical connections 80 are embedded in flexible printed circuits 82 (Figs. 4 and 5) which are fixedly or removably attached to face mask 70 and extend along adjustable band 74. The electrical connections 80 typically terminate at a single connector 84 located on the face mask 70 or within a cable 86 which extends from the face mask 70.

Flexible printed circuits 82 can be molded directly onto face mask 70. Alternatively, they can be formed into a soft plastic ribbon or otherwise surrounded with electrical and mechanical insulation. The soft plastic ribbon can then be removably mounted to face mask 70 using renewable adhesive pads or other renewable binding means.

Additionally, in accordance with a preferred embodiment of the present invention, preamplification, transient protection and bandpass filtering circuits, described in more detail hereinbelow with reference to Fig. 6, are associated with face mask 70 for each pair of electrode assemblies 10 attached to face mask 70. The circuits for the entirety of the pairs of electrode assemblies 10 corresponding to each eye are preferably incorporated as a hybrid circuit in signal processors 88 and 90 attached to frame 71. By attaching signal processors 88 and 90 to the frame 71, noise pickup caused by cabling is reduced.

Moreover, since the majority of the biosignals to be measured will be measured as differential signals, a reference signal is provided for common mode rejection. This is provided by a reference electrode 92 preferably comprised of a silver impregnated cloth electrode, such as the E301 or E331 electrode manufactured by In-Vivo Metric.

As mentioned hereinabove, signal processing equipment is typically provided with face mask 70. It typically comprises a power supply 94 for supplying the required voltages to the electrode assemblies 10 of the face mask 70 and amplifiers 96 for further conditioning and processing of the preamplified biosignals received from signal processors 88 and 90. Specifically, the electrode assembly 10 and the signal processors 88 and 90 normally require power in the 10 - 500 milliwatt range.

Further digital signal processing, such as frequency analysis, may occur in digital circuitry 98. It will be appreciated that power supply 94, amplifiers 96 and digital circuitry 98 are typically located separately from face mask 70. It will also be appreciated that single connector 84 enables face mask 70 to be readily and easily separatable from the signal processing equipment.

Specific reference is now made to Fig. 5 which details elements of one of the flexible printed circuit boards 82. Shown are the electrical connections 80 which bring the voltage from power supply 94 to the electrode assembly 10 and bring to the amplifiers 96 the desired differential biosignals from signal processor 88. Specifically, connections 80a and 80b provide voltage to the electrode assembly 10 and to the signal processor 88, connection 80c connects to reference electrode 92, and connections 80d and 80e provide preamplified, filtered signals from the two pairs of electrode assemblies 10.

In order to obtain a differential signal between the pair of electrodes 10c and 10d on the temples, the two connections 80f are both connected to connector 84. Connections 80f are connected to electrodes 10c and 10d and are located on the respective flexible printed circuit boards 82. The differential signal is then typically created in one of signal processors 88 and 90.

The section of flexible circuit board 82 on which lies electrode 10e is preferably bent in order to match the curvature of the area between the eye and the nose bridge.

Reference is now made to Fig. 6 which illustrates a typical circuit for preamplification, transient protection and bandpass filtering of a single differential signal acquired from a pair of electrodes and a reference electrode. The circuit is believed to be self-explanatory and therefore, in the interest of conciseness, a full description will not be given. It will be noted that the components are selected to provide low and high frequency cutoffs at predetermined frequencies, such as 0.5 and 200 Hz.

The circuit of Fig. 6 is replicated for each differential voltage signal to be measured and is implemented as a single hybrid circuit. Signal processors 88 and 90 typically contain at least one circuit such as is shown in Fig. 6.

Referring back to Figs. 1 - 5, face mask 70 is utilized as follows. Preparatory to placing the face mask 70 on a subject's face, an operator attaches cover sheet assemblies 76 and 78 to face mask 70 by snapping together the contact pairs 18 and 32 and 20 and 34. Typically, the mask 70 is then placed onto the subject's face, and the adjustable bridge 71 is adjusted, if necessary. Finally, connector 84 is attached to cables connected to the signal processing equipment. The electrode assemblies 10 are in their proper location and

are now ready to obtain measurements. No further adjustments are required. In this manner, the electrodes are placed on a subject with ease.

It is a feature of the present invention that an operator does not need to be skilled in skin or electrode preparation or in electrode placement to utilize the face mask 70 of the present invention. With little work on the part of the operator and little discomfort to the subject, the apparatus 70 is ready to obtain the desired biosignals.

It will be appreciated that the apparatus 70 can be utilized for determining a vertical and/or horizontal gaze position relative to the position of the head. As is known in the art, the horizontal and vertical components of the three-dimensional gaze angle, defined here as the horizontal and vertical gaze positions, increase monotonically with the amplitude of the EOG signal obtained from vertical and horizontal pairs of electrodes, respectively. The relationship between the gaze position and the amplitude of the EOG signal is obtained by having the subject observe targets at known angular positions relative to "straight ahead" as is common practice in neurological tests of EOG and eye movements.

As mentioned hereinabove, the vertical EOG is obtained from a pair of electrodes, illustrated in Fig. 5 as 10a and 10g or 10b and 10h, which are typically located above and below one eye, respectively. The horizontal EOG is obtained from the pair of electrodes 10g and 10i which are typically placed near the outer canthus of each eye.

The gaze position can be utilized in an eye mouse, an apparatus for providing one or two-dimensional positional input to a computer, providing much the same information as that provided by a mechanical mouse.

The eye mouse is utilized as follows: while keeping his head fixed, a subject calibrates the eye

mouse by looking at a predetermined calibration position on the computer screen or within his field of view and by confirming through some standard input route, such as via a keyboard or a mechanical mouse button, that he is looking at the calibration position known to the computer.

Computer software, implementing equations 1 - 6 hereinbelow, receives the horizontal and vertical EOG amplitudes, after low pass filtering by digital circuitry 98 to remove transients and sudden jerks or other high frequency noises or artifacts, and associates them with the predetermined calibration position.

While maintaining his head in a fixed position, the subject then looks at a second predetermined calibration point at a location significantly horizontally and vertically far from the first predetermined calibration point and confirms his gaze as described hereinabove. The computer software receives the EOG amplitudes for the second point and computes from them, from the first EOG amplitudes, and from the coordinates of the two calibration points, a relationship between the subject's horizontal and vertical EOG amplitudes, EX and EY respectively, and the position X, Y of a point at which the subject is gazing for a given distance and orientation of the head relative to the computer screen.

The X, Y position of the point is typically a linear function of the EOG amplitudes EX and EY as follows:

$$X = AX*EX + BX \quad (1)$$

$$Y = AY*EY + BY \quad (2)$$

where AX, AY, BX and BY are defined as follows:

$$AX = (X2 - X1)/(EX2 - EX1) \quad (3)$$

$$BX = X1 - AX*EX1 \quad (4)$$

$$AY = (Y2 - Y1)/(EY2 - EY1) \quad (5)$$

$$BY = Y1 - AY*EY1 \quad (6)$$

and where (X1, Y1) and (X2, Y2) are the computer

coordinates of the respective calibration points. X2 is different from X1 and Y2 is different from Y1. EX1 and EX2 are the horizontal EOG amplitudes received when the subject looked at points (X1, Y1) and (X2, Y2) and EY1 and EY2 are the vertical EOG amplitudes received when the subject looked at points (X1, Y1) and (X2, Y2).

Alternatively, in a second calibration method, the subject can look sequentially at the points of a grid or other set (X1, Y1), (X2, Y2), ..., (Xn, Yn), known to the computer, with each point having an associated measured (EXn, EYn). A two-dimensional mathematical function relating true (Xi, Yi) to measured (EXi, EYi) is thus sampled.

By fitting the sampled lattice of points (Xi, Yi) for given values (EXi, EYi) with linear, polynominal or other mathematical models known in the art, any position (X, Y) can be estimated from the measured (EX, EY) of an arbitrary point as long as the subject's head maintains a fixed orientation and distance relative to the calibration points.

In either of the abovementioned calibration methods, upon moving his head, the subject indicates to the computer by keypad or similar input means that his head is being repositioned. When a new position is taken, the subject indicates via the above means that he is ready for the computer to redefine the new position. The computer sequentially displays one or more points, generally fewer than in the original calibration set, and the subject sequentially moves only his eyes to focus on the most recent point thereby to indicate to the computer when each point is in view. If the subject has not rotated his head or moved it substantially (i.e. the mapping of the eye position to the computer position is basically the same but the offset BX, BY has changed), then typically a single calibration point can be used to identify the new position of his eye.

In this manner, the eye mouse can be utilized

for indicating position information to the computer.

It will be appreciated that the eye mouse remains calibrated only as long as the subject's head remains in a constant position relative to the screen.

Reference is now made to Figs. 7A - 7C which illustrate alternative embodiments of the present invention for use in easily acquiring brain, eye, scalp muscle and facial activity signals. In Fig. 7A, electrode apparatus, such as electrode assemblies 40, are mounted onto a cap or hat shaped element 100, similar to a hat commonly sold to sports fans, in appropriate locations for acquiring electro-encephalograph (EEG) signals.

In one preferred embodiment, the electrode assemblies 40 are located along the midline of the skull wherein electrode assemblies 40d and 40e are at the central and occipital regions, respectively, and electrode assemblies 40a, 40b and 40c are on the forehead. Electrode assemblies 40i and 40j are held against the skin in the areas behind the ears via extensions of the cap element 100.

A reference electrode 41, such as described hereinabove, is preferably located on the forehead. Alternatively, electrode assembly 40 are placed at a multiplicity of points on the skull corresponding to the international 10 - 20 system of EEG electrode placement. In this alternative embodiment, the output of the electrode assembly 40, after appropriate amplification, can be utilized, for example, in standard commercial polygraphic stripchart or brain mapping analysis systems.

Either electrode placement configuration, incorporated alternatively into a close-fitting pilot flight helmet as shown in Fig. 7B and described in more detail hereinbelow, can be used to detect the pilot's EEG, EOG and EMG signals. Such an apparatus can be utilized for detecting changes in pilot status such as

loss of consciousness.

As in the previous embodiment of the present invention, the electrode assembly 40 are typically mounted to the cap element 100 via an appropriately shaped flexible printed circuit (not shown). As in the previous embodiment, an integrated cover sheet assembly, of the type shown in Fig. 2, can be utilized; the integrated cover sheet assembly in this embodiment would be a single skull cap composed of a multiplicity of cover sheet assemblies 42. Cap 100 is adjustable to ensure that it firmly fits to any size head.

Fig. 7B illustrates the apparatus of the present invention embedded in a pilot flight helmet 102. The apparatus comprises a plurality of capacitive electrodes 14 ranged about the face of a subject, with or without the use of a cover sheet assembly. A reference electrode 104, such as a silver impregnated cloth electrode, provides a reference signal for the apparatus and is typically located near the subject's forehead.

Flexible wires 106 extend from the electrodes to an internal wiring connector 108, typically placed inside the helmet 102. A pre-amplifier can be included in wiring connector 108 and the output of the connector 108 is typically connected to circuitry (not shown) such as that shown in Fig. 4. A microphone outlet 110 is typically included in such flight helmets and is operative, in this embodiment, to provide a convenient access from the connector 108 to the circuitry.

Typically, a standard pilot flight helmet is retrofitted to produce the apparatus shown in Fig. 7B. Fig. 7C illustrates this operation. A pilot flight helmet typically comprises a helmet and padding (not shown) covered by a typically leather liner 112. A plurality of access holes 114 are cut into the liner 112 of the helmet 102 and capacitive electrodes 14 are placed into them. Reference electrode 104 is attached

to the skin-side of liner 112 and its connecting wiring is passed through a small hole (not shown) in liner 112 towards internal wiring connector 108.

An individual cover sheet assembly 116 can be placed over each capacitive electrode 14, or a single cover sheet assembly 118 can be placed over a plurality of capacitive electrodes 14. The covers 116 and 118 are operative to keep sweat and dirt away from the capacitive electrodes 14 and are typically non-conductive. If cover 118 is utilized, then reference electrode 104 is located on the pilot's skin side of cover 118.

Alternatively, the padding which is covered by liner 112 can be augmented by, or replaced by, padding of appropriate shape and thickness which already contains the aforementioned electrodes and wiring circuitry.

Reference is now made to Fig. 8 which illustrates another alternate embodiment of the present invention for use in easily acquiring spontaneous or evoked muscle activity signals, as well as photopletheysmographic measurements of blood flow and heart rate.

In this embodiment, the apparatus for rapidly applying electrodes comprises a modified glove 120 onto which are mounted, via the elements described hereinabove, two standard conductive electrodes 122, such as the silver impregnated cloth electrode manufactured by In-Vivo Metric, for providing electrical stimuli to the hand, two capacitive electrode assemblies 10 for acquiring EMG signals in response to the signals provided by the electrodes 122, and a photo-pletheysmographic sensor 124, such as a light source and photodiode combination found in the Model 6390 Omni-Sat ear sensor by Critikon of Tampa, Fl. of the USA, for providing blood flow data. This apparatus is useful for measuring neuromuscular transmission across the wrist,

in order to determine deliberate muscle relaxation during surgery or intensive care, while simultaneously monitoring relative blood flow in the finger.

As in the previous two embodiments of the present invention, glove 120 is elastic and has an adjustable band on the back to ensure that it fits firmly to any size hand.

It is a feature of the present invention that common articles of clothing are used to mount the various electrode assemblies to the subject's body. This helps to make the subject comfortable with the testing to be performed by the apparatus of the present invention and it ensures that the both the subject and the operator know how to place the article of clothing on the body.

A further embodiment of the present invention, shown in Figs. 9A, 9B and 9C, is useful for detecting and responding to drowsiness, or pre-sleep behavior, of a subject. In this embodiment of the invention, labeled 130, electrode assemblies 10 are typically mounted on a frame 131 whose function is similar to that of frame 71. The electrode assemblies 10q - 10t are located near the outer canthi of the eyes, temples and/or below the eyes for measuring the EOG and other eye-related signals. The electrode assemblies 10q - 10t are typically located as close to the eyes as comfortably possible, preferably without restricting the subject's visual field. A reference electrode 132, such as a silver impregnated cloth electrode manufactured by In-Vivo Metric, is also mounted onto frame 131. By placing the electrode assemblies 10 close to the eyes, the efficiency of the signal acquisition is maximized and spurious pickup of brainwaves (the electroencephalogram or EEG) is minimized.

Alternatively, electrode 10q can be located behind the ear of the side of the head opposite to electrode 10t, which may be located anywhere around the

eye or forehead.

Frame 131 can be any close fitting frame or clothing which can place a plurality of electrode assemblies near the eyes. A minimal set of electrode assemblies includes one above one eye, one at a reference location and another near an eye or behind the ear, contralateral to the electrode assemblies above the eye. Examples of such frames are: an eyeglass frame, a face mask, a cap, goggles, a headband or headphones.

Apparatus 130 optionally comprises head motion sensors 134a and 134b. These can be electrodes such as the E220 silver/silver-chloride electrodes manufactured by In-Vivo Metric or any standard metallic electrode type, and are used in conjunction with signal conditioning equipment for detecting low frequency signals. Alternatively, head motion sensors 134a and 134b can be accelerometric motion detectors, used in conjunction with appropriate signal conditioning equipment. Head sensors 134a and 134b are mounted on frame 131 in a location which ensures that they are not in contact with the subject's skin, thereby ensuring that they do not pick up any bioelectric signals but instead, measure only head motion.

The biosignals and optional head motion signals are collected via flexible circuit boards 136, one of which is shown in Fig. 13, which are similar to the ones described hereinabove with reference to Fig. 5. Flexible circuit boards 136 can be fixedly or removably attached to the frame 131, as described hereinabove. Typically, if frame 131 is the subject's eyeglasses, the flexible circuit boards 136 are removably attached.

The signals are sent, via a cable 138, to processing means 140, described in more detail hereinbelow. An integrated cover sheet assembly (not shown) is also optionally included.

Apparatus 130 is typically utilized for passively and non-obtrusively monitoring a subject for

signs of drowsiness. Such an apparatus can be used for monitoring truck drivers or other personnel in jobs in which they must not fall asleep. To ensure that the subjects do not fall asleep, the processing means 140 comprise a detector module 142 for detecting behavior associated with an increased risk of falling asleep, known hereinafter as the drowsiness condition, and an alerting module 144 for alerting the subject upon the detection of drowsiness. Processing means 140 are typically powered by a power supply 146.

In accordance with a preferred embodiment of the present invention, the alerting module 144 typically activates a loudspeaker 148, such as an earphone, a hearing-aid type speaker, or a small speaker incorporated into alerting module 144, located near the subject, to produce an audible alerting sound. Upon detection of the drowsiness condition, the alerting module 144 produces the alerting sound at a low intensity and increases the intensity until the subject responds, typically by blinking or by moving the head. In one embodiment, to prevent accommodation by the subject, the alerting sound is alternatively selected by the alerting module 144 from among a multiplicity of different recorded or programmed sounds such that the same sound is never used to alert the subject twice in a row. Alternatively, the same sound may be used two or more times in a row.

Pre-sleep behavior, typically occurring for many seconds before the onset of sleep, tends to be characterized by quiescent behavior and the relaxation of facial muscles. Conversely, awake behavior is characterized at least in part by eye, facial and head movements, blinking, and or talking. The bioelectric signals to be obtained from the vicinity of the eyes while a subject is awake have substantial signal amplitudes in a high frequency range of typically 30 - 1500 Hz. and in a low frequency range of typically

1 - 10 Hz. Conversely, the average amplitudes of the biosignals obtained at the onset of drowsiness are much smaller than those obtained from an awake subject. The high frequency range typically characterizes muscle activity and the low frequency range typically characterizes eye movements, blinks and motion artifacts.

In a preferred embodiment of the present invention, the alerting module 144 is to be activated whenever the amplitudes of the biosignals in the low and/or high frequency ranges drop substantially below baseline values, measured when the subject is awake, for more than a selectable number of seconds. The baseline values may be recorded during a set-up period occurring at the beginning of the use of the apparatus 130 or they may be updated periodically during use of the apparatus 130.

Typical RMS amplitude curves of biosignals representing a several minute period in which a typical subject falls asleep are shown in Figs. 10A and 10B. The biosignals are from electrode assemblies 10 located near the eyes. The abscissas of the graphs in Figs. 10A and 10B are in minutes and the ordinates are in arbitrary amplitude units proportional to an integrated average RMS amplitude of the signal in its pass band. The pass band for the low frequency signal is 0.5 - 10 Hz and the pass band for the high frequency signal is 30 - 1500 Hz.

In Fig. 10A, curve 150 is the actual RMS amplitude of the high frequency portion of the biosignal, averaged using a moving window of a duration of typically a few seconds. Curve 152 is a typical baseline curve calculated by averaging the RMS values of the biosignal using a moving 1 - 2 minute window ending 30 - 60 seconds before the current time.

It will be appreciated that at a point 154 in time, the high frequency activity drops below a

predetermined threshold level, marked 156. In Fig. 10A, threshold level 156 is 50% of the current baseline value. As shown in Fig. 10A, point 154 stays below threshold level 156 for longer than a predetermined period T1, typically 10 - 20 seconds. The end of period T1 marks the achievement of the drowsiness condition and is the activation point of the alerting module 144. The actual onset of sleep, characterized by very low amplitude levels and indicated by reference numeral 158, typically occurs after the activation point of the alerting module 144, assuming that the alerting module 144 has not been activated. Figs. 10A and 10B illustrate the typical behavior of the biosignals in which the alerting module 144 is not activated.

Fig. 10B illustrates the low frequency behavior of a typical biosignal from electrodes placed near the eyes where curve 160 is the low frequency RMS amplitude curve similar to curve 150. Curve 162 is a typical baseline curve calculated as described hereinabove. In Fig. 10B, the predetermined threshold level, marked 166, is typically 50% and the predetermined period is marked T2. At point 168, the onset of sleep occurs.

It will be appreciated that the alerting module 144 can be activated when one of the two curves 150 or 160 achieves the drowsiness condition or when both simultaneously indicate the drowsiness condition, or when one achieves the drowsiness condition and the other achieves it within a predetermined period of time.

Additionally, alerting module 144 can be periodically activated to check that the subject is still alert. In such an embodiment, the time from the alert until the subject responds, herein denoted the response time, is measured. Alerting module 144 can also be activated in relation to the length of the response time or the length of time a subject remains active or quiescent after previously being alerted.

Head motions are optionally detected by head motion sensors 134a and 134b for those applications which involve substantial head motion. Their signals are processed in a manner similar to that of the low frequency range signals described hereinabove. The head motion activity is then removed from the low and high frequency biosignals by means of real-time adaptive filtering software such as that described in chapter 9, "Adaptive Filtering," of Biomedical Signal Processing: Vol. 1, written by Arnon Cohen, published by CRC Press, Boca Raton, Fl. in 1986 and incorporated herein by reference.

Subject response to the alert is detected by means of the acquisition electronics as described hereinabove. Response detection is achieved by comparing the present amplitude to that which immediately preceded the alert. A substantial increase is construed as a subject response.

Alternatively, the present amplitude is compared to that recorded when the subject is known to be aware and alert. Alternatively, the present amplitude is compared to a peak amplitude obtained when the subject is blinking but is otherwise quiescent, or the signal is compared to a waveform of representative blinks recorded when the subject is otherwise quiescent, using matched filter or cross correlation methods such as those presented in the above reference by Arnon Cohen.

Each time the alerting module 144 is activated, the response detection means are activated and the response time is measured. The response time is additionally compared to the previous response time. If the response time has increased, typically indicating an increase in drowsiness, the time between periodic alerting is decreased.

Furthermore, the alerting module 144 is operative to gradually increase the intensity of the

audible sound until the response detection means indicate that a response has been measured.

The processing means 140 are detailed in Fig. 11 to which reference is now made. Detector module 144 comprises two preamplifiers 172, of the type described with reference to Fig. 6, for amplifying by a gain of typically 500 to 1000, differential biosignals received from two pairs of electrode assemblies 10. Preamplifiers 172 are not incorporated into the processing means 140 if the incoming signals are received from signal processors 88 on frame 131. Each preamplifier 172 receives signals from one pair of electrode assemblies 10.

The two amplified signals are sent to a pair of identical low frequency band pass filters 174 for filtering frequencies in a pass band of typically 1 - 10 Hz and to a pair of identical high frequency band pass filters 176 for filtering frequencies in a pass band of typically 100 - 1500 Hz. Filters 174 and 176 attenuate frequencies outside their respective pass bands by at least 12 dB per octave.

Signal processors 178 typically receive the filtered high frequency signals from filters 176 and rectify, peak sense and integrate them, producing relatively smooth signals. The resultant signals are proportional to the peak-to-peak amplitude of the filtered high frequency signals and have a limited bandwidth of typically 0 - 100 Hz. A typical signal processor 178 is shown in Fig. 12 where integrated circuits V_1 are the TL064 chips manufactured by Motorola and integrated circuits V_2 are the LM393 chips, manufactured by National Semiconductor.

Amplifier pairs 180 and 182 amplify the respective filtered low and high frequency signals received, respectively, from filters 174 and processors 178, to an amplitude in the range of a few, typically 1 - 5, volts.

An A/D converter 184, typically a multichannel A/D converter having one channel for each electrode assembly pair input, converts the amplified signals from amplifiers 180 and 182 to four digital signals of at least $2N_i$ samples per second, where N_i is the bandwidth of the ith channel. The resolution of the samples is typically eight bits. A/D converter 184 can optionally be a combination of an A/D converter and a multiplexer.

A microprocessor 186, typically a low power consuming microprocessor such as the Motorola 68HC11, processes the four digital signals in accordance with the method described hereinabove with reference to Figs. 10A and 10B. At the appropriate moments, the microprocessor 186 activates alerting module 144, described in more detail hereinbelow. Software pseudocode outlining the operation of the microprocessor 186 is incorporated herein in Annex A.

Alerting module 144 comprises an audio generator 188, such as a tone or voice synthesizer, which is controlled by microprocessor 186, for producing one of a multitude of preprogrammed tone signals or sounds stored in microprocessor 186, and an audio amplifier 190, such as a Walkman audio amplifier manufactured by Sony of Japan, for amplifying the tone signals produced by the audio generator 188. Audio amplifier 190 is also controlled by microprocessor 186 to enable the alerting module 144 to vary the amplitude of the alerting sound according to the subject's response or lack thereof. The tone signals emanating from audio amplifier 190 are made audible by loudspeaker 148.

Reference is now made to Figs. 14A - 14C which respectively illustrate front, back and side views of an embodiment of a fetal biosignal probe 200 using any of the electrode assemblies of Fig. 1.

The probe 200 typically comprises a capacitive electrode assembly 202, such as described hereinabove particularly with respect to Fig. 1, and a wiring cable

204 for connecting the electrode 202 to a data processing system, described in more detail hereinbelow with respect to Fig. 16.

The electrode 202 and wiring cable 204 are typically embedded in a relatively flat probe body 206 which is typically comprised of a stiff but flexible material, such as nylon or other common plastic, and is of sufficient length to reach from a fetal scalp to completely outside the mother's cervix. A typical length is between 40 - 50 cm.

The probe 200 additionally comprises a reference electrode 208 for providing an electrical reference signal, similar to those described hereinabove in Fig. 1. The reference electrode 208 is mounted on an outer surface 210 of body 206 facing the fetal scalp and its wiring 212 is embedded in body 206.

The wiring cables 204 and 212 may comprise a flexible printed circuits whose wires serve to provide the wiring to electrodes 202 and 208, in a manner similar to that illustrated in Fig. 5.

On the outer scalp-side surface 210 of probe 200 is a frictionous or adherent area 214 for enabling the probe 200 to adhere to the scalp of the fetus, thereby preventing the probe 200 from slipping relative to the surface of the scalp. Frictionous area 214 is typically comprised of a layer of ribbed, soft rubber such as that used for dishwashing gloves, such as manufactured by Playtex, Inc. of the USA. A surface 216, on the opposite side of the probe from surface 210, includes a smooth surface 218, on the opposite side of the probe 200 from area 214, for enabling generally easy slippage of the probe 200 against the uterine wall.

The probe 200 is typically operated as follows. During labor, the probe 200 is inserted into the uterus of the mother and is positioned in a desired position on the scalp of a fetus. Area 214 and surface 218 enable the probe 200 to travel with the fetal head

as it emerges during delivery.

Reference is now made to Figs. 15A - 15C which respectively illustrate front, back and side views of an alternative embodiment of fetal biosignal probe 200 using the electrode of Fig. 1. Similar reference numerals refer to similar elements.

In this embodiment, the probe 200 is optionally used in conjunction with a cover sheath 220 which covers the entire length of probe 200 and is preferably made of a thin plastic, such as polyethylene or other common plastic. Sheath 220 is preferably sterile and is preferably disposable.

The reference electrode 208 is mounted on an outer surface 222 of sheath 220 facing the fetal scalp. The electrode wiring, here also labeled 212, passes through the wall of sheath 220 and runs down its length to where it exits the sheath 220. In this embodiment, the frictionous or adherent area, here labeled 224, is similar to that described above, and is on the outer surface 222 of sheath 220. The smooth surface, here labeled 226, is on an outer surface 228 of sheath 220.

Reference is now made to Fig. 16 which illustrates a system for obtaining fetal biosignals during delivery using at least two probes 200 of either of the abovementioned embodiments.

The system typically comprises at least two probes 200 for obtaining differential fetal signals typically placed on opposite sides of the fetus's head. The system also comprises signal processing equipment similar to those described hereinabove with reference to Fig. 4.

Specifically, the signal processing equipment comprises amplifiers 230, connected to probe 200 via electrode wiring 212 and wiring cable 204, digital circuitry 240 and a power supply 245. In this configuration, however, the probes 200 will acquire fetal ECG signals in addition to fetal EEG signals.

This complicates the EEG analysis. Therefore, to remove the fetal ECG signal from the total acquired signal, an ECG amplifier 250, such as a Hewlett Packard fetal monitor model 8030 or 8040, is included in the signal processing equipment. The output of amplifiers 230 and the ECG signal from amplifier 250 are typically input to digital circuitry 240 containing real-time adaptive filter software 260, such as described in Chapter 9 of the book Biomedical Signal Processing: Vol. 1 of Arnon Cohen. Software 260 removes the fetal ECG signal from the differential biosignal obtained from probes 200, providing the EEG and EMG signals free of ECG artifact.

The ECG amplifier 250 preferably obtains the unamplified biosignals from one of probes 200 via the input connections to amplifiers 230. A maternal electrical reference signal can be provided via a maternal reference electrode 270, such as the standard silver/silver-chloride gel disposable type disclosed hereinabove, typically placed on the mother's thigh. Alternatively, ECG amplifier 250 can be incorporated into amplifiers 230.

If only the fetal ECG signal is desired, a single fetal probe 200 and the maternal reference electrode 270, can be used in conjunction with ECG amplifier 250.

Reference is now made to Figs. 17 and 18 which respectively illustrate apparatus for accurately measuring a true Critical Flicker Fusion Test (CFFT) frequency score of a subject constructed and operative in accordance with a preferred embodiment of the present application and electronics to drive the apparatus.

One psychological test of particular importance for the detection of impaired cognitive function is the CFFT. Numerous clinical studies have documented the effects of various drugs, fatigue and other factors on the CFFT. Many of them are reported in the article "Critical Flicker Frequency and Psychotropic

Drugs in Normal Human Subjects - A Review", by Smith and Misiak, published in Psychopharmacology, Vol. 47, pp. 175 - 182, 1976. These studies have shown that a reduced CFFT frequency score can be indicative of impairment of cognitive functions, such as reaction time, visual perception and decision making.

In the CFFT, a subject observes a light source whose intensity varies according to an oscillation frequency. The subject is required to specify the highest oscillation frequency, known as the critical flicker fusion frequency, at which the light source appears to flicker. For frequencies greater than the critical frequency, the light source is perceived by the subject to be constantly lit, denoted herein as supercritical non-flicker; for frequencies less than the critical frequency, the light source appears to flicker.

The purpose of the present invention is to provide a reliable CFFT score even for subjects who may have an interest in trying to avoid providing an accurate estimate of the CFFT. Such action by a subject is likely if a low or reduced CFFT frequency score indicates that the subject has an impairment.

The apparatus of the present invention, an embodiment of which is shown in Fig. 17, makes it highly improbable for a subject to claim a higher CFFT frequency than his true CFFT frequency. This is achieved by requiring the subject to identify a pattern of flickering light sources embedded or associated with surrounding non-flickering light sources which are either constant (DC) in their intensity or supercritically non-flickering. The non-flickering sources are otherwise identical in appearance to the flickering sources. In the following discussion, the light sources are LEDs it being understood that any light source capable of rapid intensity modulation is suitable.

A preferred embodiment of the apparatus

comprises a set of 12 identical LEDs 300 capable of rapid intensity oscillation, arranged in a circular pattern similar to a clock face. Other patterns of multiple light sources, such as linear arrays, matrices or dot arrays can alternatively be employed. Driving electronic circuitry 302, shown in detail in Fig. 18, under the control of a computer 304 supplies oscillating electric signals to the LEDs 300, thereby causing their intensities to vary accordingly. The subject communicates with the computer 304 via an input keyboard 306 or similar input means.

The LEDs 300 are divided into two groups, a background group 308 and a flicker group 310. The flicker group 310 comprises at least one LED. The LEDs of the background group 308 are oscillated at a frequency far greater than any known CFFT frequency, typically 250 Hz, or are held at a constant (DC) intensity. Any frequency can be used to drive the LEDs of the flicker group 310. The oscillations are generally sinusoidal although other alternating patterns can be used.

The operation of the apparatus is as follows. LEDs of the flicker group 310 are initially oscillated at a frequency of approximately 60 Hz, a frequency known to be above the critical flicker frequency. The oscillation frequency of the flicker group 310 is reduced, typically at a rate of 1 Hz per second, until the subject identifies to the computer 304 via the keyboard 306 that he detects at least one of the LEDs 300 flickering. The computer 304 then stops reducing the oscillation frequency of the flicker group 310.

The recording of the subject's CFFT frequency score is dependent on his identifying the correct flicker group. Incorrect identification of the flicker group can be indicative of a deliberate attempt to gain a fraudulent score.

For example, assuming that just the LED in the

6 o'clock position belongs to the flicker group 310, the subject has only a 1 in 12 chance of guessing correctly the flickering LED before his true CFFT is reached. If two LEDs are used, the subject has less than a 1% chance of correctly pinpointing which LEDs are flickering before his true CFFT is reached.

Not only does the proposed apparatus prevent a subject from deliberately raising his true CFFT, but the subject is also unlikely to report a CFFT below his true readout. This is because the subject, after detecting flickering of one of the LEDs, is not likely to waste time in trying to recognize the entire flicker group while the oscillation frequency continues to drop, thereby giving a CFFT score below his true score. Instead, the subject is more likely to first notify the computer 304 that he has detected flickering in at least one of the LEDs. He can then identify the other flickering LEDs without lowering his score.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the claims which follow:

ANNEX A

MAIN SOFTWARE PSEUDO-CODE


```
begin program
10   initialize variables

       Quiet_Threshold          [under which signal considered quiet]
       Response_Threshold       [over which signal considered active]
       QIWmax                   [max allowable quiet period]
       QIWmin                   [min allowable quiet period]
       QIWincr                  [penalty/reward increment]
       Quiet_Time_Window        [max allowable quiet period, using BSR & parms]
       Active_Time_Window       [min fixed time between alarms]
       Time_Since_Alarm         [time since last alarm was sounded]
       Response_Window          [max allowed time for response to alarm]
       Response_Time_Min        [min contiguous response required to turn off]
       BSR_Array                [used to compute Burst Supression Ratio]
       contig_quiet_count       [contiguous quiet samples]
       contig_response_count    [contiguous active samples]

20   get user input parameters

30   activate 10 alarms         [initialize reaction time baseline]
     measure 10 reaction times
     compute average reaction time

40   do forever                 [main loop]
     {

50    get next sample of activity data

60    if (sample is below Quiet_Threshold)

62        increment contig_quiet_count       [count contiguous quiet samples]

64    else

66        reset contig_quiet_count to 0      [contiguity broken]

70    if (sample is above Response_Threshold)

72        increment contig_response_count

74    else

76        reset contig_response_count to 0       [contiguity broken]
```

MAIN SOFTWARE PSEUDO-CODE


```
70    if (alarm is sounding)        [check whether to turn off alarm]
      {
80        if (contig_response_count is greater than Response_Time_Min)
          {
82            if (first alarm level)
83                    increment QIWincr          [reward fast response]
84            else
              {
85                    set QIWinc to 0            [slow response penalty]
86                    reset BSR_Array to all quiet values
              }
87            turn off alarm
           }
90        else          [no response yet to alarm]
92                if (time alarm sounding exceeds Response_Window)
94                    elevate alarm intensity level
          }
100       add new sample to BSR_Array              [BSR is % time in BSR array
          recalculate Burst Supression Ratio        below Quiet_Threshold]
110       recalculate Quiet_Time_Window:
          Quiet_Time_Window =
                QIWmax -
                   (Burst Supression Ratio * (QIWmax - QIWmin)) + QIWincr
          bounded by QIWmax and QIWmin              [QIWmax < Q_T_W < QIWmin]
```

MAIN SOFTWARE PSEUDO-CODE


```
120     count Time_Since_Alarm        [keep track of time between alarms]
130     decide whether to sound Lack of Activity alarm:
132     if (contig_quiet_count exceeds Quiet_Time_Window)  AND
134        (alarm is not currently sounding)
        {
136             sound first level alarm
138             reset Time_Since_Alarm to 0    [start counting again]
        }
140     decide whether to sound Time alarm:
142     if (Time_Since_Alarm exceeds Active_Time_Window)
        {
146          sound first level alarm
148          reset Time_Since_Alarm to 0        [start counting again]
         }
    }       [end main loop]
```

C L A I M S

1. Apparatus for mounting electrodes on a human body in order to obtain human biosignals comprising:

close fitting clothing means;

a plurality of electrodes mounted to said close fitting clothing means;

removable cover sheet means for providing a sterile interface between the skin and at least one of said electrodes; and

joining means for joining said removable cover sheet means to at least one of said plurality of electrodes.

2. Apparatus according to claim 1, and also including flexible circuit means for mounting said plurality of electrodes onto said close fitting clothing means.

3. Apparatus according to claim 2, and wherein said flexible circuit means are fixedly attached to said close fitting frame.

4. Apparatus according to claim 2, and wherein said flexible circuit means are removably attached to said close fitting frame.

5. Apparatus according to claim 2, and also comprising signal processing means mounted on said flexible circuit means for preamplifying, transient protecting and filtering at least one differential biosignal obtained between signals received from two of said electrodes.

6. Apparatus according to claim 1, and also comprising signal processing means for preamplifying, transient protecting and filtering at least one differential biosignal obtained between signals received from two of said electrodes.

7. Apparatus according to claim 1, and wherein said removable cover sheet means include reference means for providing a reference signal for at least one of said plurality of electrodes.

8. Apparatus according to claim 7, and wherein said joining means include electrical contact means between said

reference means and at least one of said plurality of electrodes.

9. Apparatus according to claim 1, and wherein said removable cover sheet means include conductive means for providing a conductive path between at least one of said plurality of electrodes and the human body.

10. Apparatus according to claim 1, and wherein said joining means are of the following group: press contact pairs, adhesive pads or Velcro (registered trademark).

11. Apparatus according to claim 1, and wherein at least one of said plurality of electrodes in a capacitive electrode.

12. Apparatus according to claim 1, and wherein said close fitting clothing means is one of the following group: a glove, a face mask, goggles, a cap, a sweat band, a head band or a helmet.

13. Apparatus according to claim 12, and also including a photoplethysmographic sensor.

14. A referenced capacitive electrode assembly for mounting on human skin comprising:

a capacitive electrode mounted in a substrate;

removable cover sheet means separate from said capacitive electrode for providing a reference signal to said capacitive electrode and for providing a separable interface between said human skin and at least one of said electrodes; and

joining means for joining said cover sheet means to said capacitive electrode.

15. Assembly according to claim 14, and wherein said joining means include electrical contact means between said cover sheet means and at least one of said plurality of electrodes.

16. Assembly according to claim 14, and wherein said removable cover sheet means include moist conductive means for providing a moist conductive path between at least one of said plurality of electrodes and said human skin.

17. Assembly according to claim 14 and wherein said joining means are one of the following group: press contact pairs, adhesive pads, or Velcro (registered trademark).

18. A referenced capacitive sensor channel assembly for mounting on human skin for the purpose of measuring bioelectric signals comprising:

a set of at least two capacitive electrodes mounted in a substrate;

removable cover sheet means separate from said set of capacitive electrodes for providing a separable interface between said human skin and at least one of said set of capacitive electrodes and including reference means for providing a reference signal for said sensor channel;

joining means for joining said cover sheet means to said set of capacitive electrodes; and

signal processing means for processing said bioelectric signals.

19. Apparatus for alerting a drowsing subject comprising:

a close fitting frame mounted on a head of said subject;

a plurality of electrodes mounted to said close fitting frame for measuring biosignal activity occurring generally in the area of the face and head of said subject;

data processing means for processing said biosignal activity into baseline curves and for determining when said biosignal activity crosses a threshold related to said baseline curves for longer than a predetermined amount of time indicating an increased risk of drowsiness;

alerting means for alerting said drowsing subject upon determination by said data processing means that a state of drowsiness has occurred; and

response detection means for detecting the subject's response to an alert issued by said alerting means.

20. Apparatus according to claim 19, and wherein at

least one of said plurality of electrodes is capacitive.

21. Apparatus according to claim 19, and wherein said alerting means include means for producing a variety of audible sounds.

22. Apparatus according to claim 21, and wherein said alerting means also include means for varying the intensity of said audible sounds.

23. Apparatus according to claim 19, and wherein said response detection means include means for measuring time to respond.

24. Apparatus according to claim 23, and wherein said means for measuring time to respond include means for comparing a current time to respond with a previous time to respond.

25. Apparatus according to claim 24, and wherein said alerting means include means for increasing the intensity of said audible sounds until said response detection means detect a response.

26. Apparatus according to claim 19, and also including a head motion sensor for detecting head motion.

27. Apparatus according to claim 19, and wherein said close fitting frame is one of the following group: a frame of a pair of eyeglasses, a frame of a face mask, a hat, a cap, or a head band.

28. Apparatus according to claim 19, and also including flexible circuit means for mounting said plurality of electrodes to said close fitting frame.

29. Apparatus according to claim 19, and wherein said mounting means are fixedly attached to said close fitting frame.

30. Apparatus according to claim 19, and wherein said mounting means are removably attached to said close fitting frame.

31. A method of alerting a drowsing subject including the steps of:

receiving biosignals from electrodes placed on and

near the face of said subject;

processing said biosignals into baseline curves and determining when amplitudes of said biosignals cross said baseline curves for longer than a predetermined amount of time indicating an increased risk of suspected drowsiness;

alerting said subject via an alerting action when said state of drowsiness is indicated; and

detecting a response to said alerting action.

32. The method of claim 31, and wherein said alerting action differs each time said increased risk of drowsiness is indicated.

33. The method of claim 31, and wherein said alerting action is an audible sound.

34. The method of claim 31, and wherein an intensity of said audible sound is initially low and intensifies until said subject gives a confirmatory response.

35. The method of claim 31, and also including the steps of measuring reaction time from initiation of an alerting action to detection of subject response, and comparing said reaction time to those of previous alerting actions thereby to estimate alertness.

36. The method of claim 31, and also including the step of periodically alerting the subject and testing the subject's reaction time even if no drowsiness is detected thereby to verify alertness.

37. Apparatus for rapidly preparing to obtain biosignals from a human body comprising:

close fitting clothing means;

a plurality of electrodes mounted to said close fitting clothing means, wherein at least one of said electrodes is a capacitive electrode; and

electrical reference means mounted to said close fitting clothing means for providing an electrical reference signal for use together with said at least one capacitive electrode.

38. Apparatus according to claim 37, and wherein said close fitting clothing means is at least part of a pilot flight helmet.

39. Apparatus according to claim 38, and also including flexible circuit means for mounting said plurality of electrodes onto said close fitting clothing means.

40. Apparatus according to claim 38, and wherein said flexible circuit means are fixedly attached to said close fitting frame.

41. Apparatus according to claim 38, and wherein said flexible circuit means are removably attached to said close fitting frame.

42. Apparatus according to claim 38, and also comprising signal processing means mounted on said flexible circuit means for preamplifying, transient protecting and filtering at least one differential biosignal obtained between signals received from two of said electrodes.

43. Apparatus according to claim 37, and also comprising signal processing means for preamplifying, transient protecting and filtering at least one differential biosignal obtained between signals received from two of said electrodes.

44. Apparatus according to claim 38, and also including a cover covering at least one of said electrodes.

45. Eye tracking apparatus for tracking the direction of a subject's gaze comprising:

close fitting clothing means mounted close to the face of said subject;

at least first and second pairs of capacitive electrodes for obtaining biosignals relating to said gaze mounted onto said close fitting clothing means wherein said first pair is mounted so as to be above and below one of said subject's eyes and wherein said second pair is mounted so as to be on opposite sides of one of said subject's eyes; and

means for converting said biosignals into position

information.

46. Eye tracking apparatus according to claim 45, and including apparatus at which to be gazed while maintaining the subject's head fixed.

47. Eye tracking apparatus according to claim 46, and wherein said means for converting include means for calibrating between said gaze and positions on said apparatus at which to be gazed.

48. A fetal biosignal probe for rapidly obtaining biosignals of a fetus comprising:

at least one capacitive electrode means mounted on a flexible body for obtaining fetal biosignals; and

reference means for providing a reference signal for said capacitive electrode means.

49. A fetal biosignal probe according to claim 48, and wherein said reference means is a conductive electrode.

50. A fetal biosignal probe according to claim 48, and wherein said reference means is mounted on said flexible body.

51. A fetal biosignal probe according to claim 48, and also including a removable cover sheath for maintaining sterility of said probe.

52. A fetal biosignal probe according to claim 51, and wherein said reference means is mounted to said cover sheath.

53. A fetal biosignal probe according to claim 48, and also including a frictionous area for enabling said probe to adhere to a portion of fetal skin.

54. A fetal biosignal probe according to claim 51, and also including an adherent area on said sheath for enabling said probe to adhere to a portion of fetal skin.

55. A system for rapidly obtaining fetal biosignals comprising:

at least two fetal biosignal probes according to claim 48 to be temporarily attached to a fetus scalp; and

signal processing means for processing fetal

electroencephalographic signals.

56. A system for rapidly obtaining biosignals of a fetus comprising:

at least one fetal biosignal probe according to claim 48 temporarily attached to a fetal scalp;

an electrode attached to skin of a mother of said fetus for receiving a maternal electrical reference signal; and

signal amplifying and filtering electronics attached to said electrode and two said fetal biosignal probe for acquiring fetal electrocardiographic biosignals.

57. System according to claim 55, and including means for providing fetal non-electroencephalograph signals and filter means for removing said fetal non-electroencephalograph from said fetal electroencephalograph signals.

58. A system according to claim 57, and wherein said means for providing fetal non-electroencephalograph signals include a fetal biosignal probe and an electrode attached to skin of a mother of said fetus for receiving a maternal electrical reference signal.

59. Apparatus for measuring a critical flicker fusion frequency of a subject comprising:

a plurality of light sources arranged in a predetermined pattern comprising a first multiplicity of background light sources and a second multiplicity of flicker group light sources;

driving circuitry means for illuminating the background light sources so as to appear non-flickering, for oscillating the flicker group light sources at a gradually decreasing oscillation frequency and for maintaining the background and flicker group light sources visually indistinguishable;

input means operated by the subject for indicating to the driving circuitry means at which frequency flicker is first observed in the flicker group and which of said

plurality of light sources belongs to the flicker group.

60. Apparatus according to claim 59, and wherein said predetermined pattern is a pattern familiar to said subject.

61. Apparatus according to claim 59, and wherein said driving circuitry means maintains a time-averaged intensity of said background group and said flicker group equivalent.

62. Apparatus according to claim 59, and wherein said pattern is a member of the group consisting of: hour positions of a clockface, number positions on a calculator keypad, number positions on a telephone keypad, linear arrays, a matrix representing an alphanumeric character, a matrix containing a pattern representing a familiar object or a matrix containing a pattern representing a familiar scene.

63. Apparatus according to claim 59, and wherein said oscillation frequency is initially set at a frequency above the highest known critical fusion frequency.

64. Apparatus according to claim 59, and wherein the background light sources are maintained at a constant intensity and thereby, do not flicker.

65. Apparatus according to claim 59, and wherein the background light sources are oscillated at a frequency above the highest known critical fusion frequency.

66. Apparatus according to claim 59, and wherein said second multiplicity is 1.

67. A method for measuring a critical flicker fusion frequency of a subject comprising:

providing a plurality of light sources arranged in a pattern familiar to a subject comprising a first multiplicity of background light sources and a second multiplicity of flicker group light sources;

illuminating the background light sources so as to appear non-flickering;

oscillating the flicker group light sources at a gradually decreasing oscillation frequency;

maintaining the background and flicker group light

sources visually indistinguishable;

requiring the subject to indicate at which frequency flicker is first observed in the flicker group and which of said plurality of light sources belongs to the flicker group light sources.

68. A method according to claim 67, and wherein the background light sources are maintained at a constant intensity.

69. A method according to claim 67, and wherein the background light sources are oscillated at a frequency above the highest known critical fusion frequency.

70. A method according to claim 67, and wherein the step of requiring comprises the step of indicating at which frequency the flicker is observed before the step of indicating which of said light sources belong to the flicker group light sources.

71. A method according to claim 67, and wherein the difference in the frequency of the background light sources and the frequency of the flicker group light sources is never less than a highest known critical flicker frequency.

72. A method according to claim 67, and including the step of maintaining a time-averaged intensity of said background group and said flicker group equivalent.

73. A method according to claim 67, and wherein said pattern is a member of the group consisting of: hour positions of a clockface, number positions on a calculator keypad, number positions on a telephone keypad, linear arrays, a matrix representing an alphanumeric character, a matrix containing a pattern representing a familiar object or a matrix containing a pattern representing a familiar scene.

74. For mounting on human skin, a capacitive electrode whose capacitive element comprises:

a housing having a skin-facing side in which there is an opening, said skin-facing side to be placed adjacent to said human skin;

a conductive element placed in said opening lying along said skin-facing side; and

a removable dielectric cover covering said opening and touching said conductive element and said human skin.

75. A referenced capacitive electrode assembly for mounting on human skin comprising:

a substrate;

a housing, mounted in said substrate, having an opening on a skin-facing face, said skin-facing face to be placed adjacent said human skin;

a conductive element placed in said opening along said skin-facing face;

a removable dielectric cover covering said opening and touching said conductive element for providing a sterile interface between said human skin and at least one of said electrodes; and

joining means for joining said cover to said substrate.

FIG. 1A

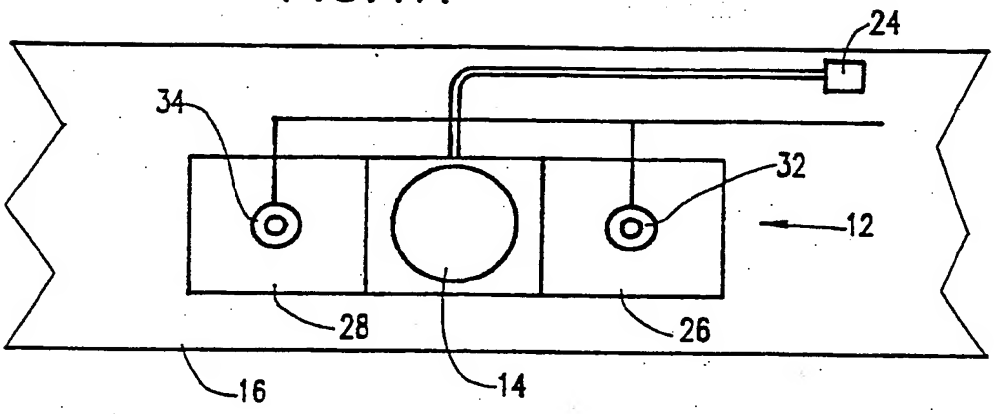


FIG. 1B

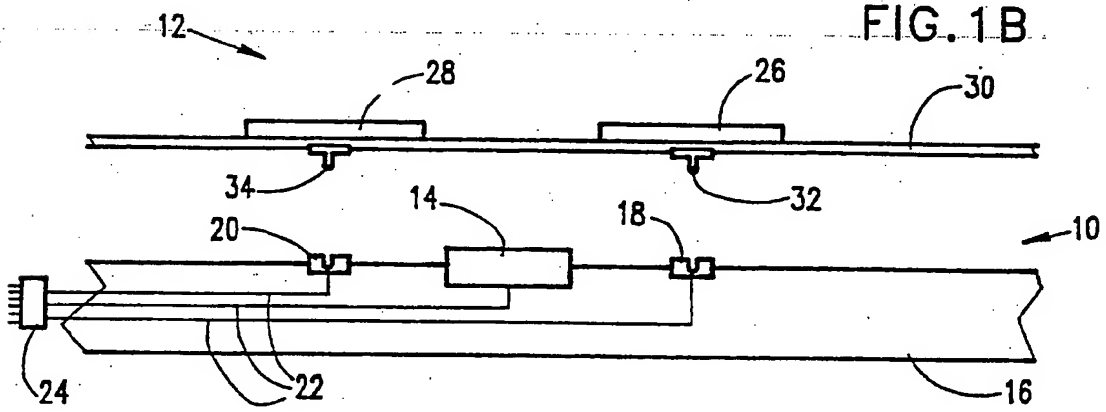


FIG. 1C

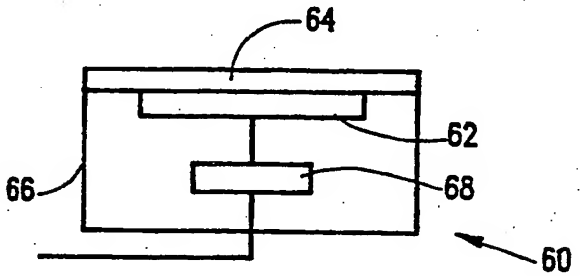
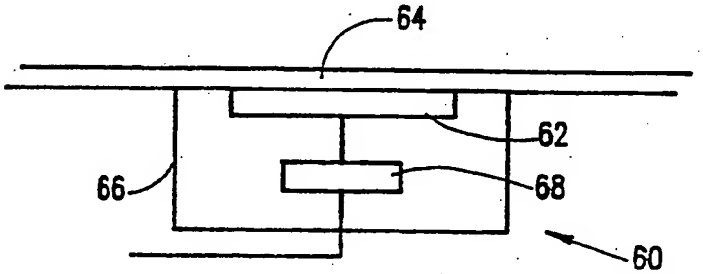


FIG. 1D



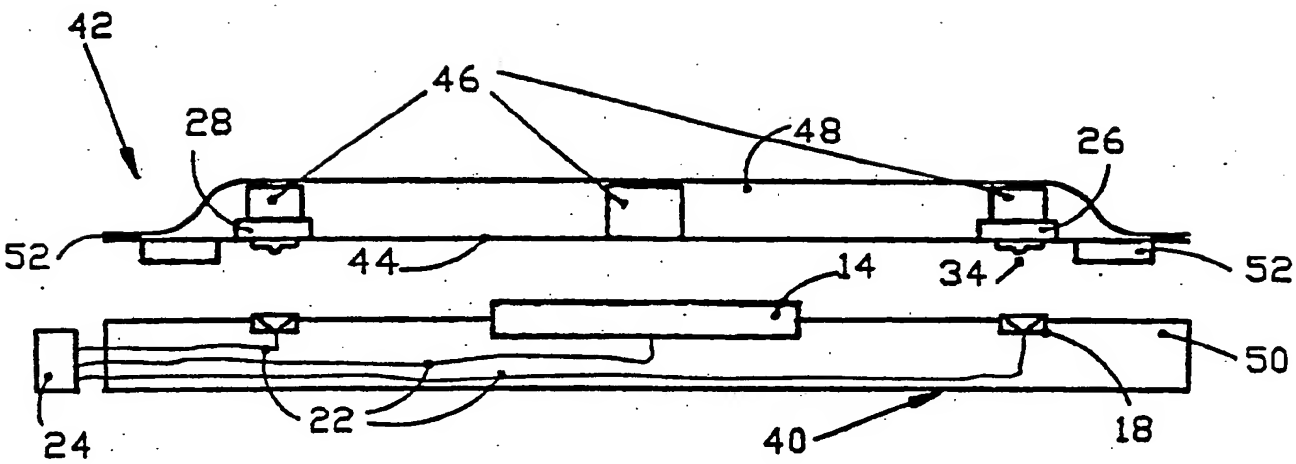


FIG. 2

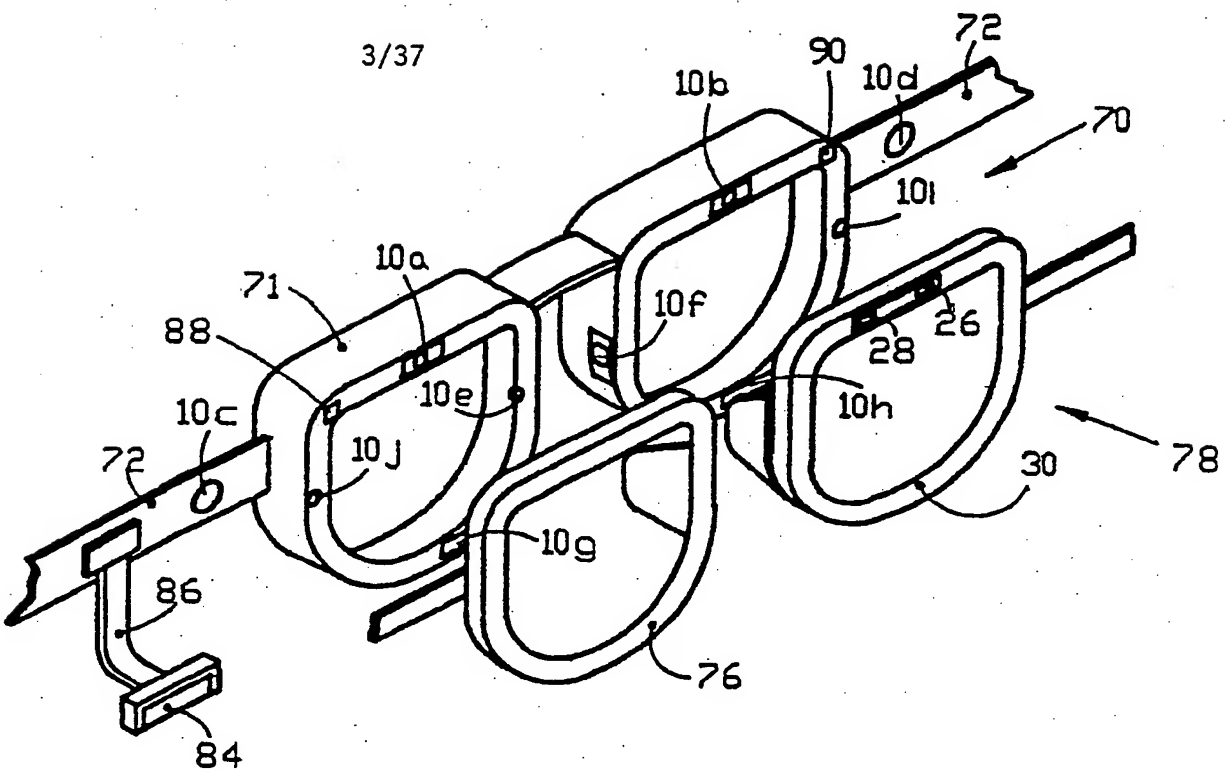

72
90
10d
10b
70
101
10a
71
88
10f
26
28
10e
10h
10c
72
10J
30
78
10g
86
76
84

FIG. 3A

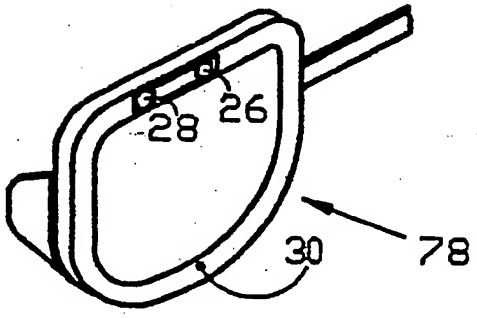
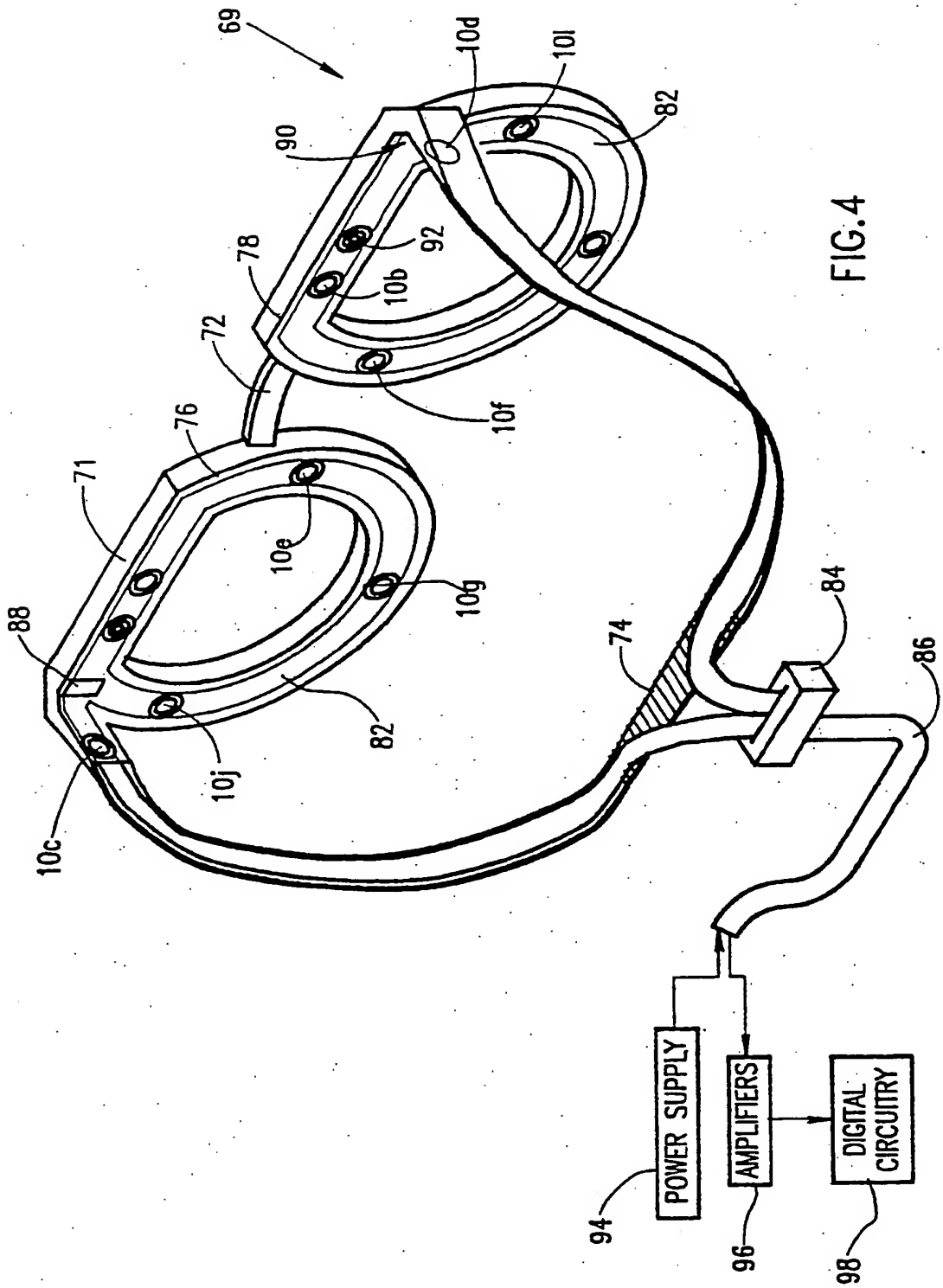

26
28
30
78

FIG. 3B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10d
10l
82
90
92
78
10b
72
10f
76
71
10e
10g
88
74
84
86
82
10j
10c
POWER SUPPLY
AMPLIFIERS
DIGITAL CIRCUITRY
94
96
98

FIG.4

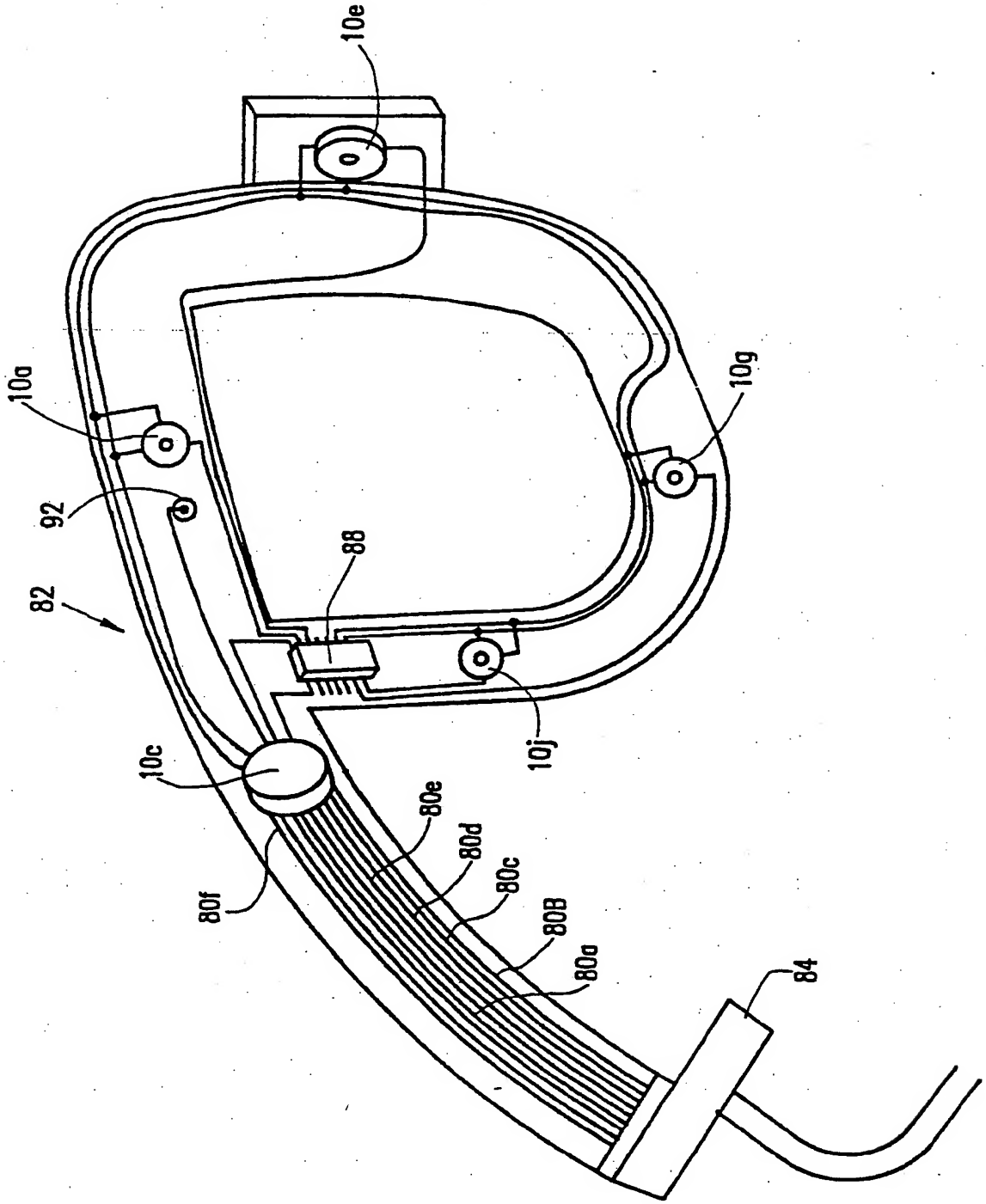
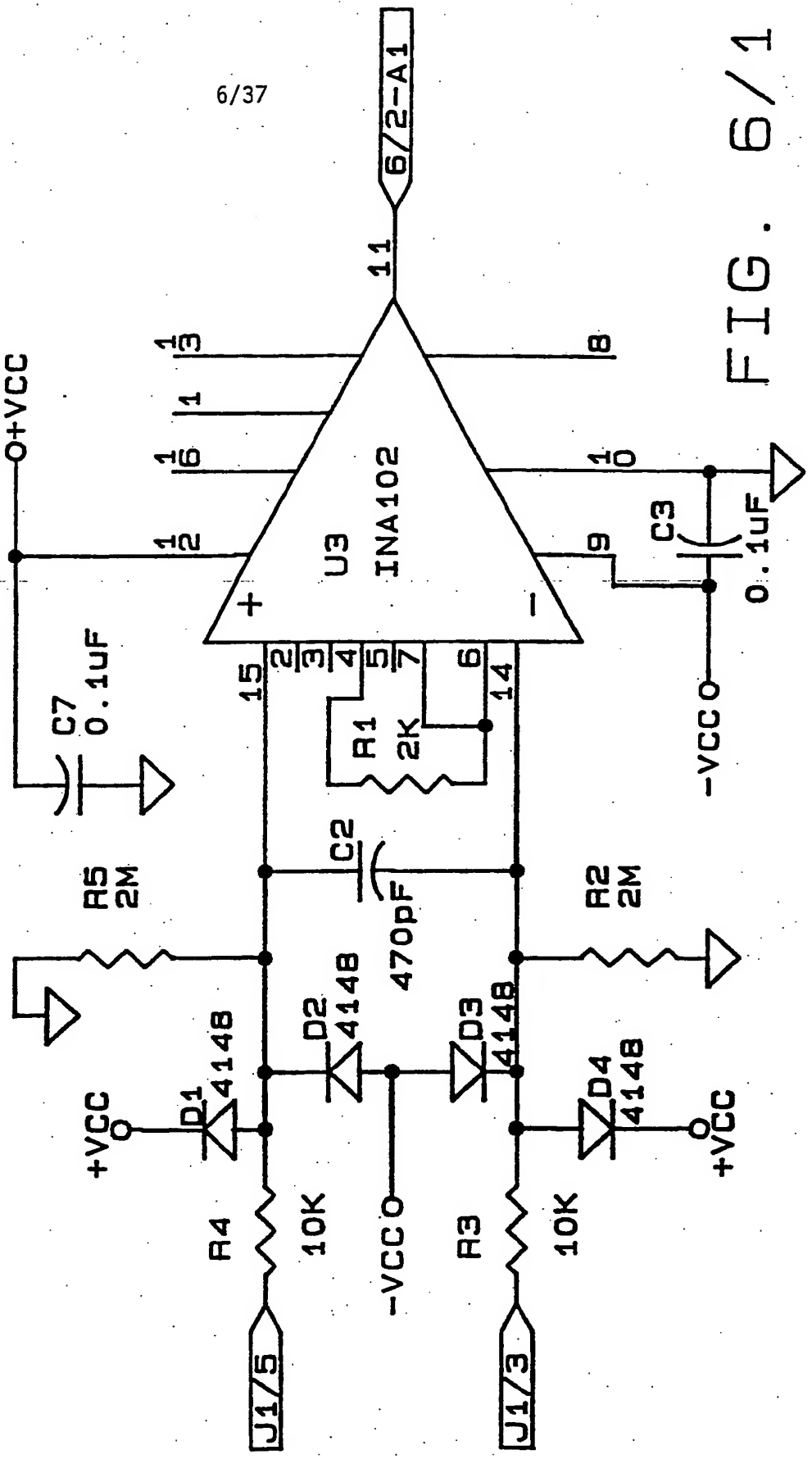


FIG.5


6/2-A1
11
13
1
16
12
8
10
9
U3
INA102
+
-
+VCC
C7
0.1uF
C3
0.1uF
-VCC
15
2
3
4
5
7
6
14
R1
2K
C2
470pF
R5
2M
R2
2M
D1
4148
D2
4148
D3
4148
D4
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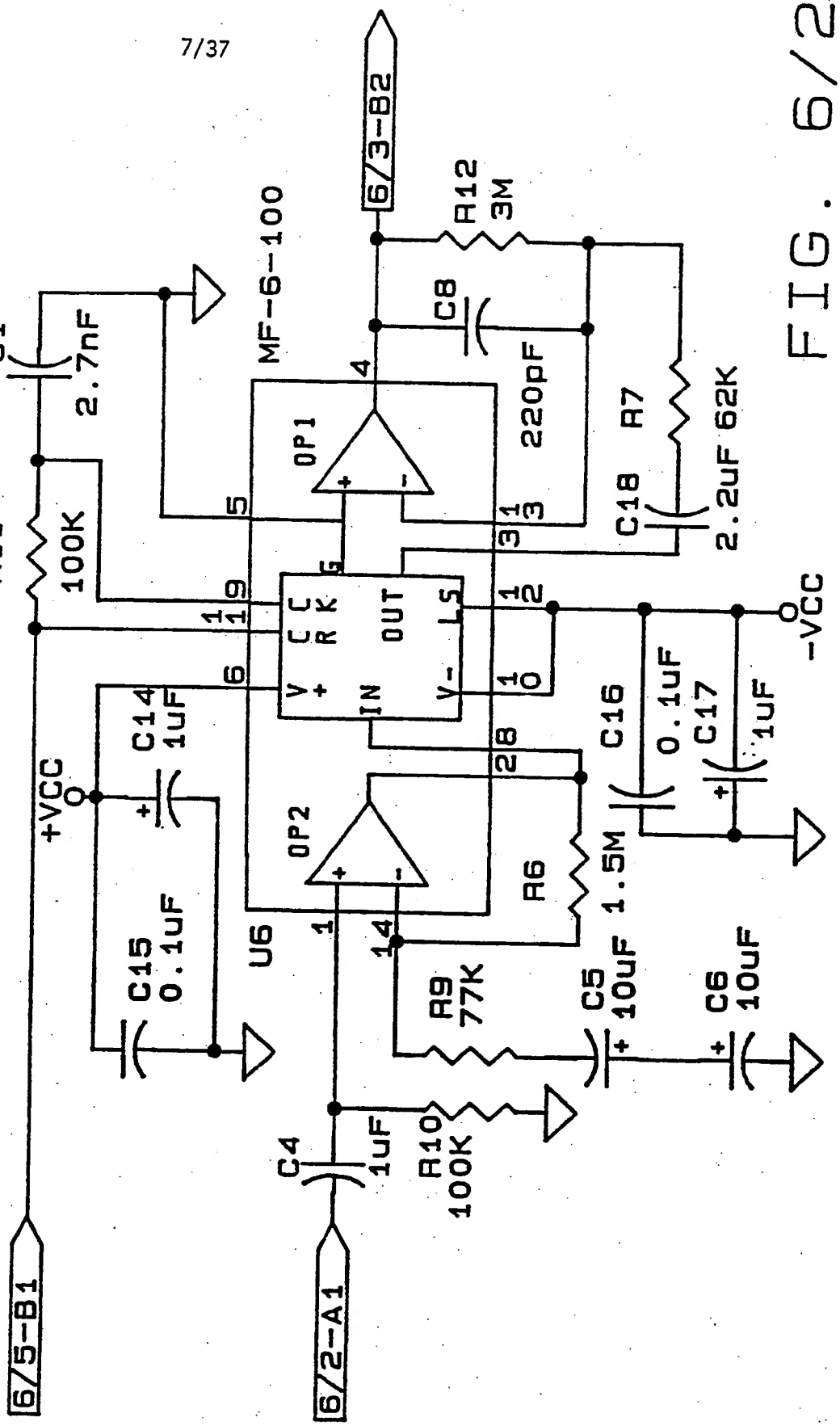
+VCC
R4
10K
-VCC
R3
10K
J1/5
J1/3

FIG. 6/1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R12
3M
C8
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MF-6-100
C1
2.7nF
OP1
R7
62K
C18
2.2uF
R11
100K
CC
RK
OUT
LS
V+
IN
V-
-VCC
C14
1uF
C16
0.1uF
C17
1uF
+VCC
OP2
R6
1.5M
C15
0.1uF
U6
R9
77K
C5
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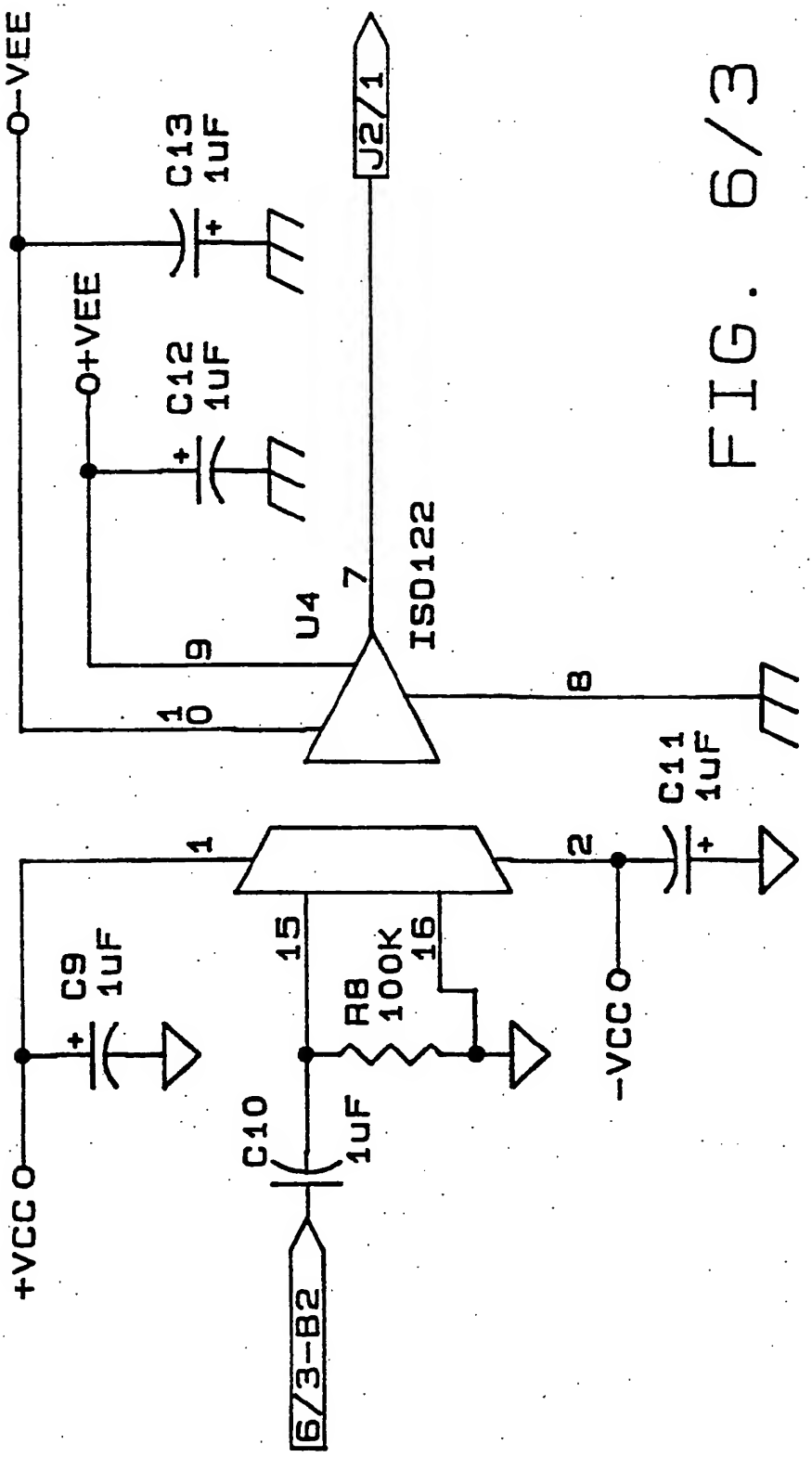
C6
10uF
C4
1uF
R10
100K
6/5-B1
6/2-A1

FIG. 6/2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C13
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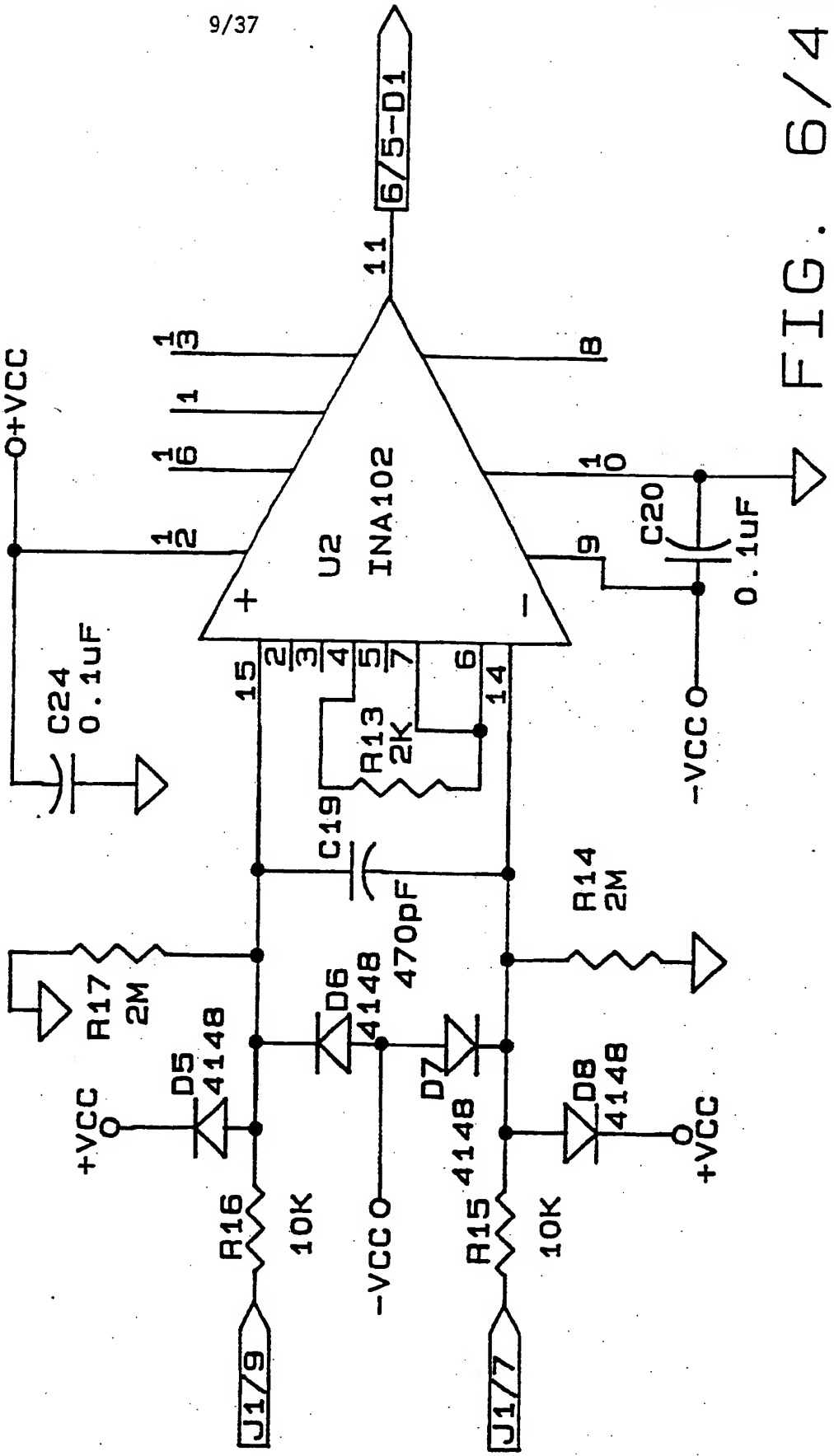
U2/1
+VEE
C12
1uF
ISO122
U4
7
9
10
8
C11
1uF
1
2
15
16
R8
100K
C9
1uF
C10
1uF
+VCC
-VCC
6/3-B2

FIG. 6/3


6/5-D1
11
U2
INA102
+
-
13
1
16
12
8
10
9
+VCC
C24
0.1uF
C20
0.1uF
-VCC
15
2
3
4
5
7
6
14
R13
2K
C19
470pF
R14
2M
R17
2M
D5
4148
D6
4148
D7
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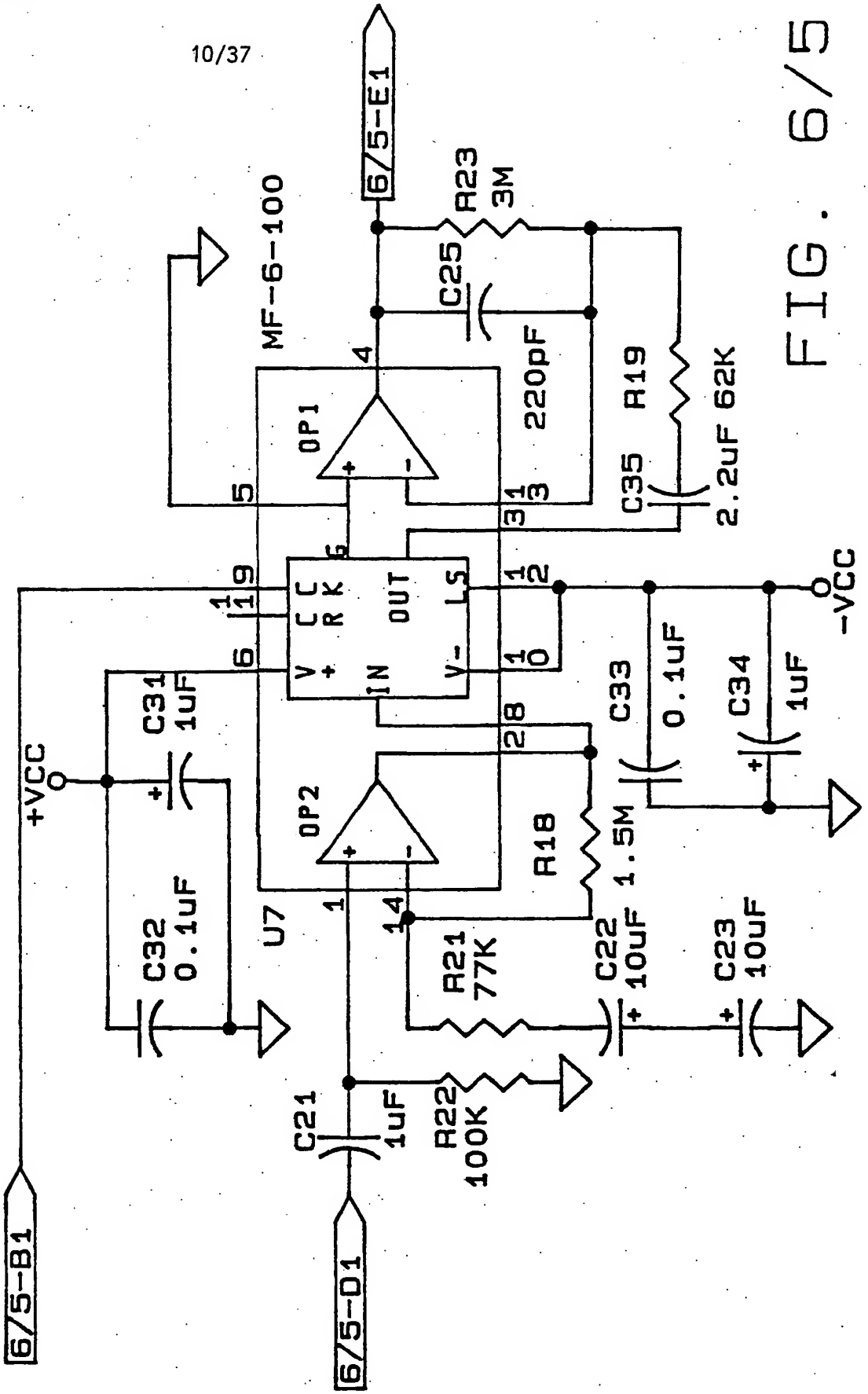
+VCC
R16
10K
R15
10K
J1/9
J1/7

FIG. 6/4


6/5-E1
R23
3M
C25
220pF
MF-6-100
OP1
R19
2.2uF 62K
C35
U7
OP2
R18
1.5M
C33
0.1uF
C34
1uF
+VCC
-VCC
C31
1uF
C32
0.1uF
R21
77K
C22
10uF
C23
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R22
100K
6/5-B1
6/5-D1

FIG. 6/5

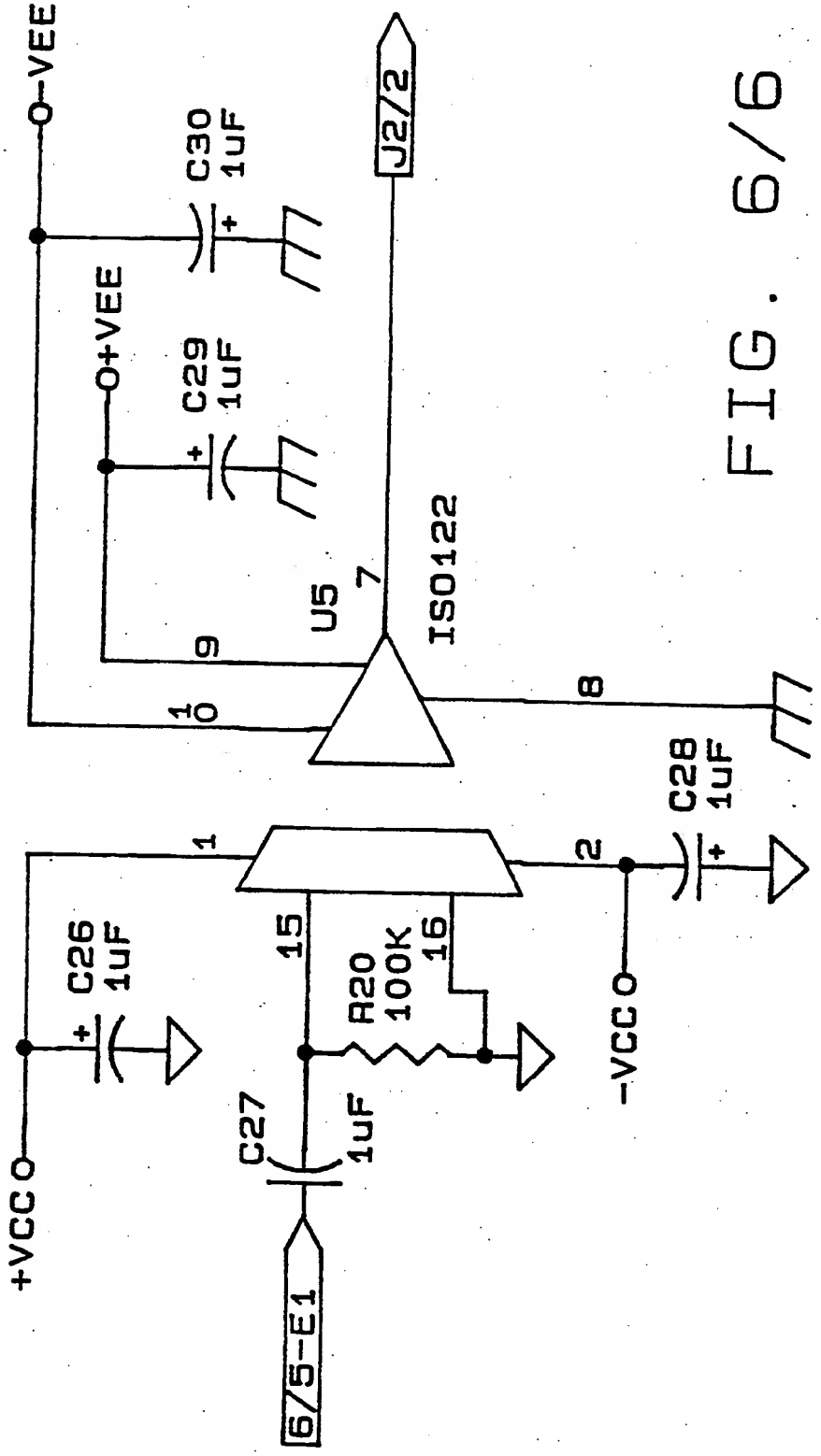

O-VEE
C30
1uF
J2/2
O+VEE
C29
1uF
U5
7
ISO122
9
10
8
C28
1uF
1
2
C26
1uF
15
R20
100K
16
-VCC O
C27
1uF
+VCC O
6/5-E1

FIG. 6/6

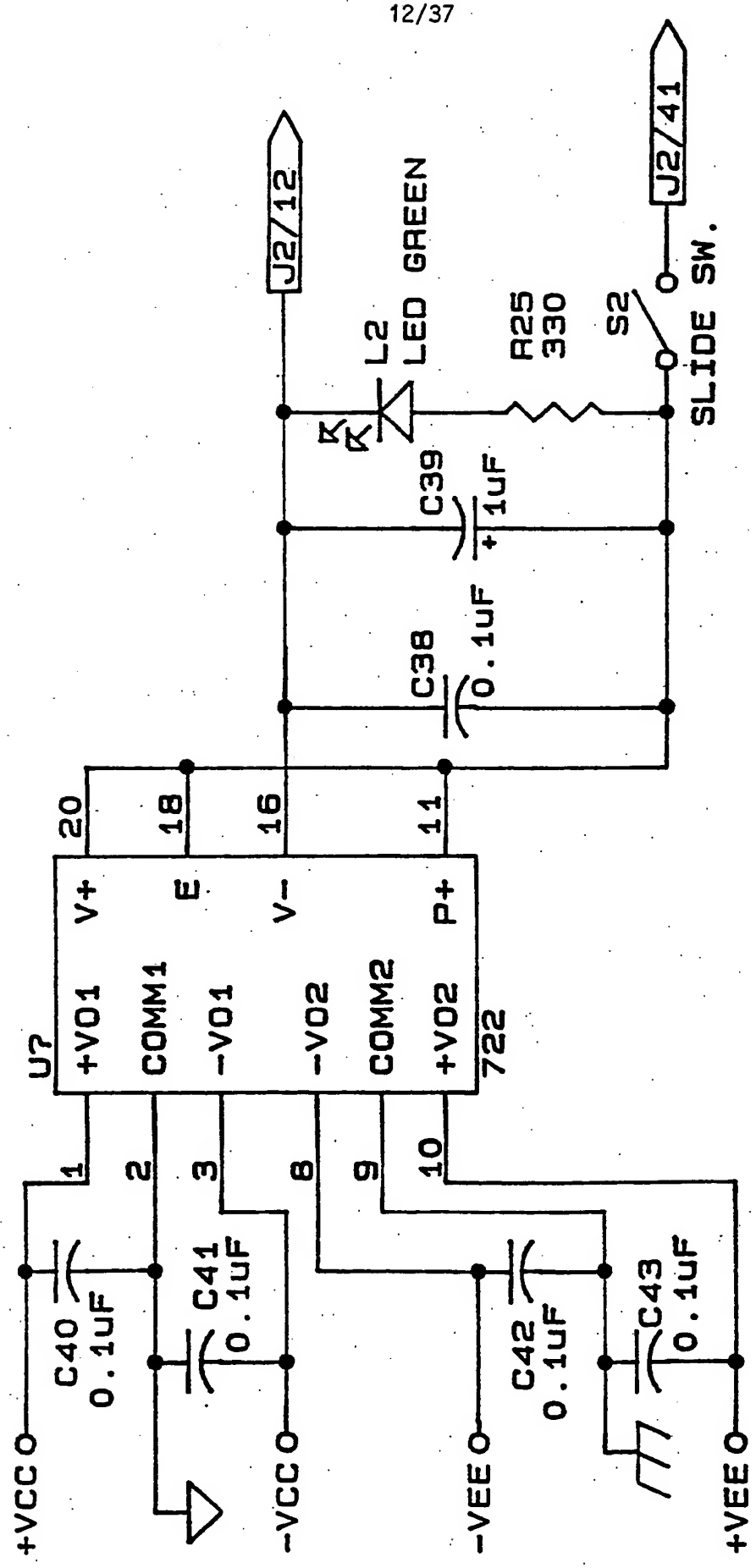

U2/12
U2/41
L2
LED GREEN
R25
330
S2
SLIDE SW.
C39
1uF
C38
0.1uF
U7
+VO1
COMM1
-VO1
-VO2
COMM2
+VO2
722
V+
E
V-
P+
20
18
16
11
1
2
3
8
9
10
C40
0.1uF
C41
0.1uF
C42
0.1uF
C43
0.1uF
+VCC
-VCC
-VEE
+VEE

FIG. 6/7

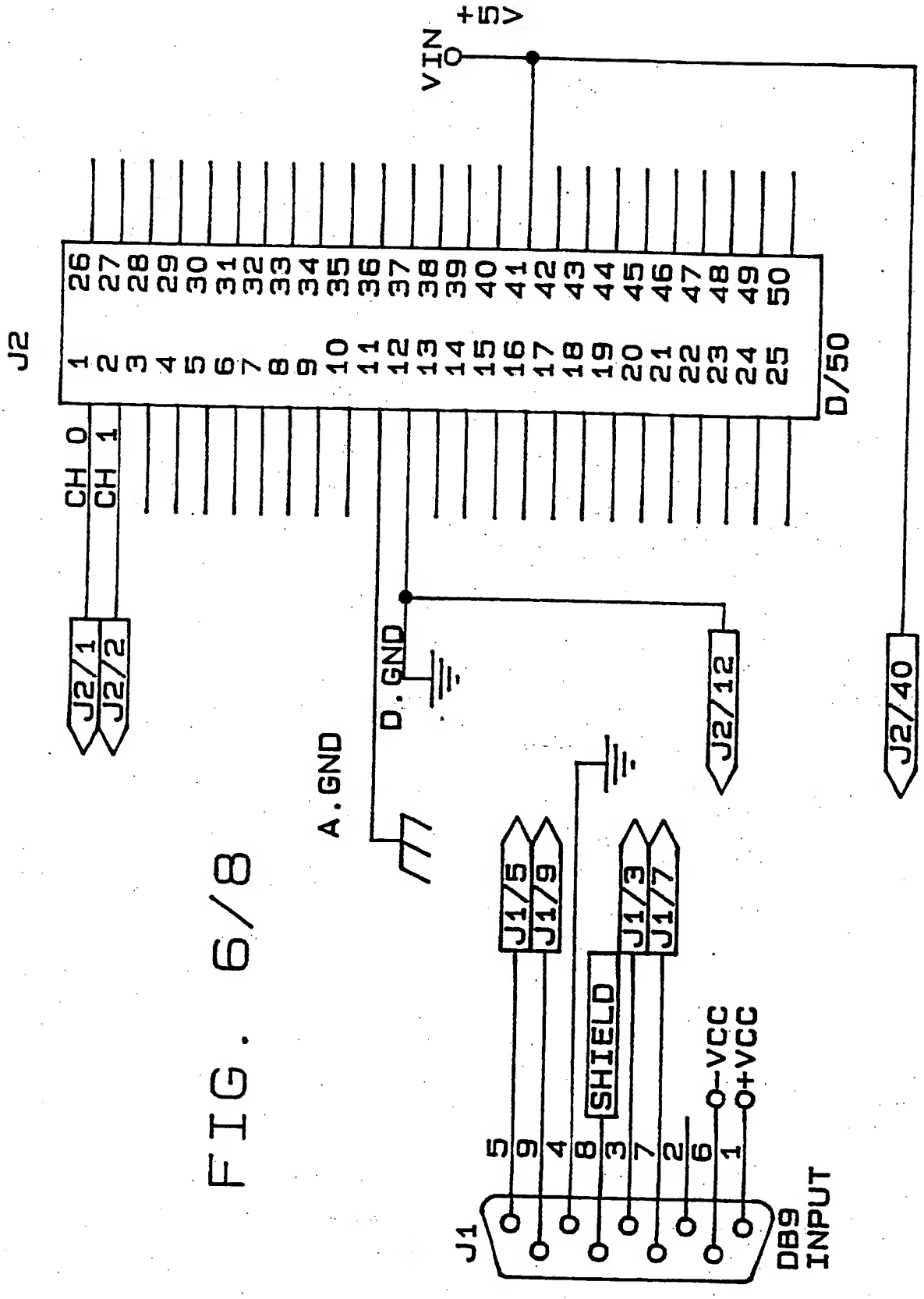

+5V
VIN
J2
D/50
CH 0
CH 1
J2/1
J2/2
D.GND
A.GND
J2/12
J2/40
J1/5
J1/9
J1/3
J1/7
SHIELD
-VCC
+VCC
J1
DB9
INPUT

FIG. 6/8

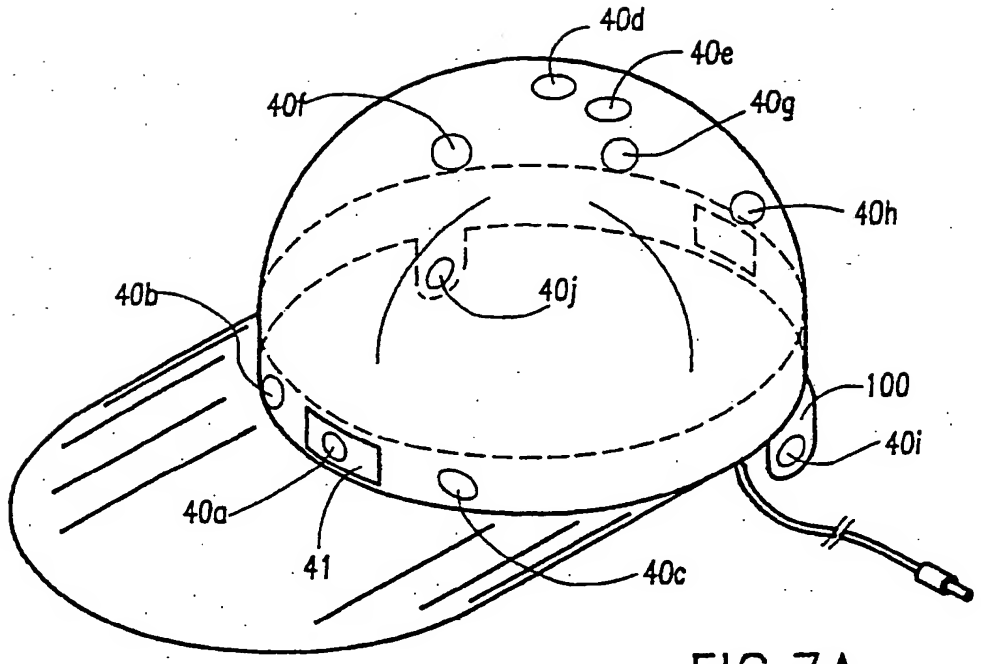


FIG.7A

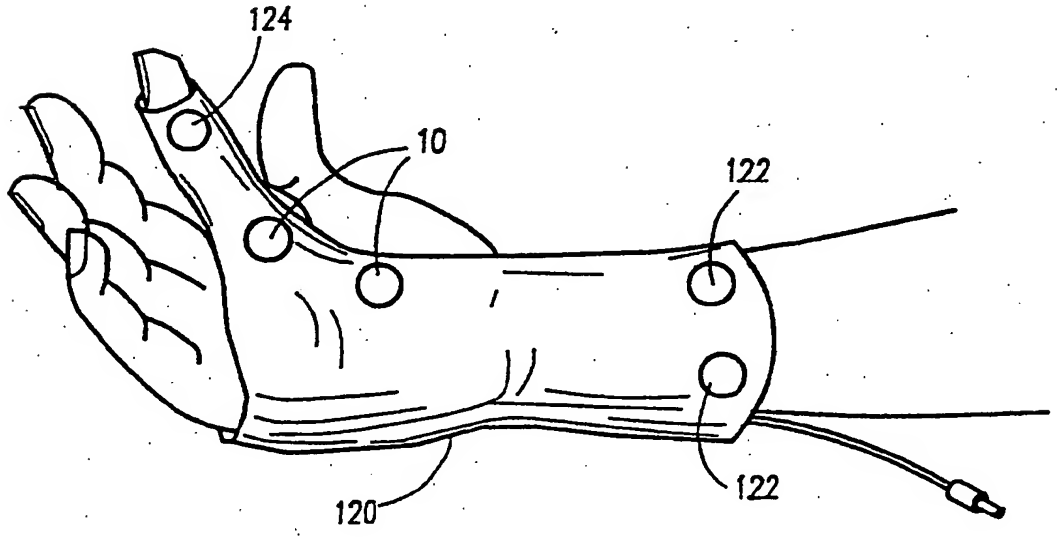


FIG.8

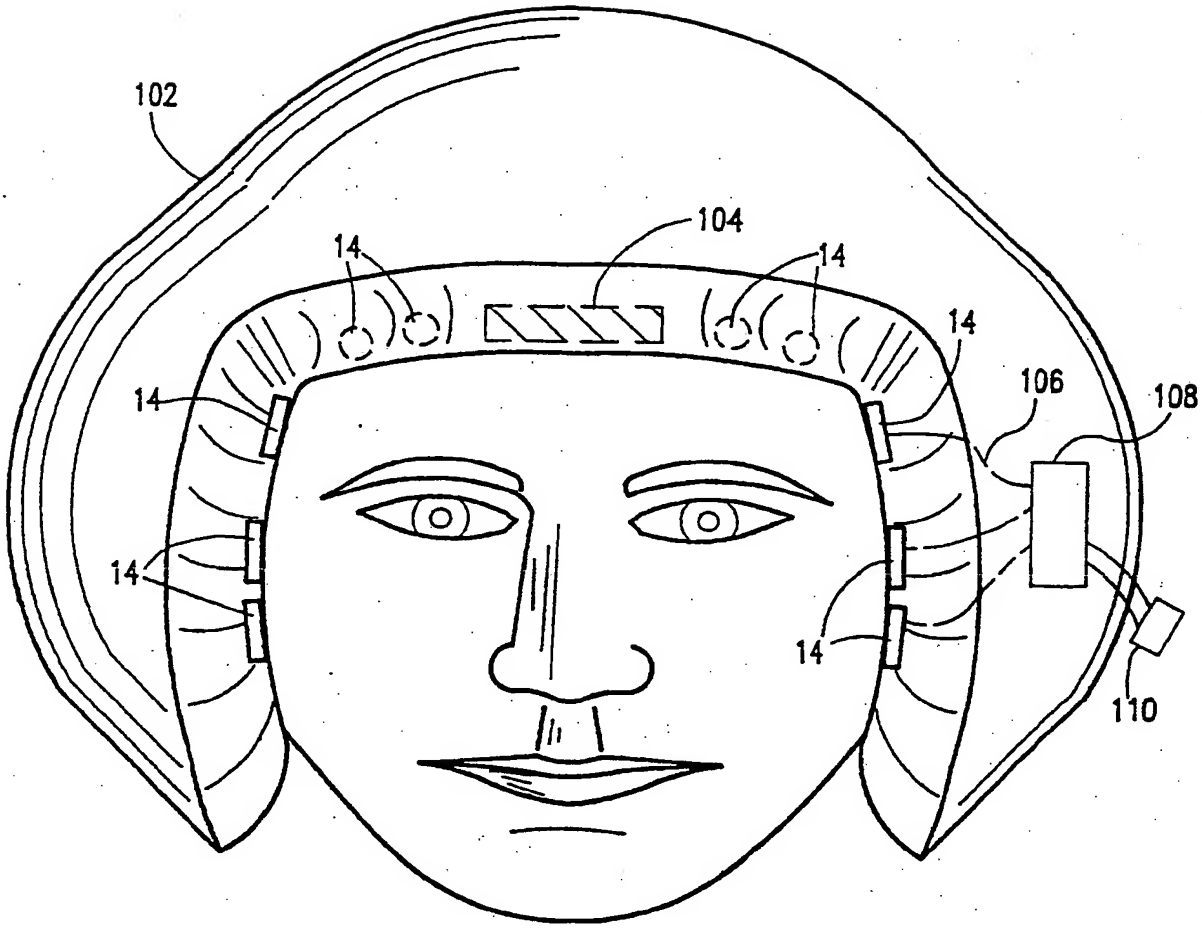


FIG.7B

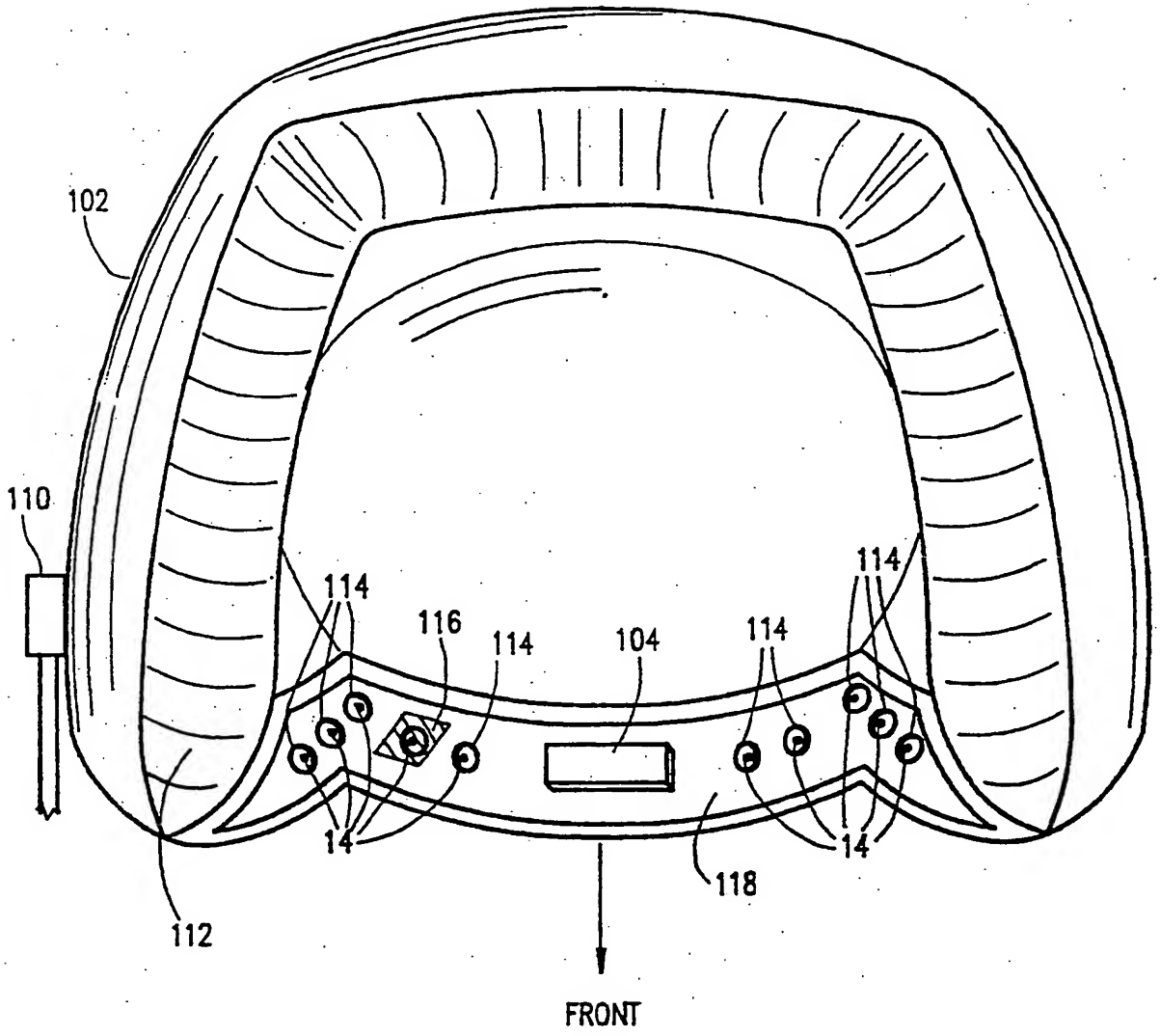


FIG.7C

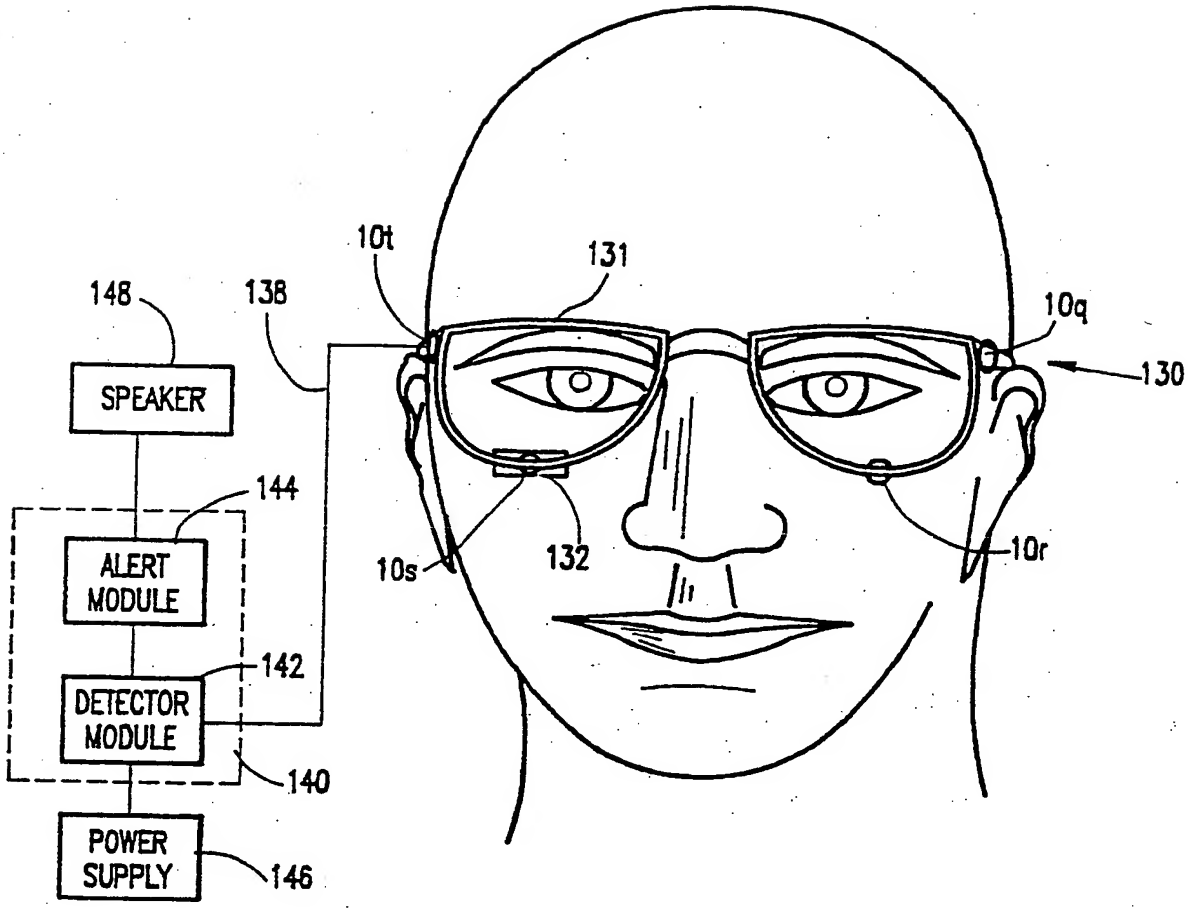
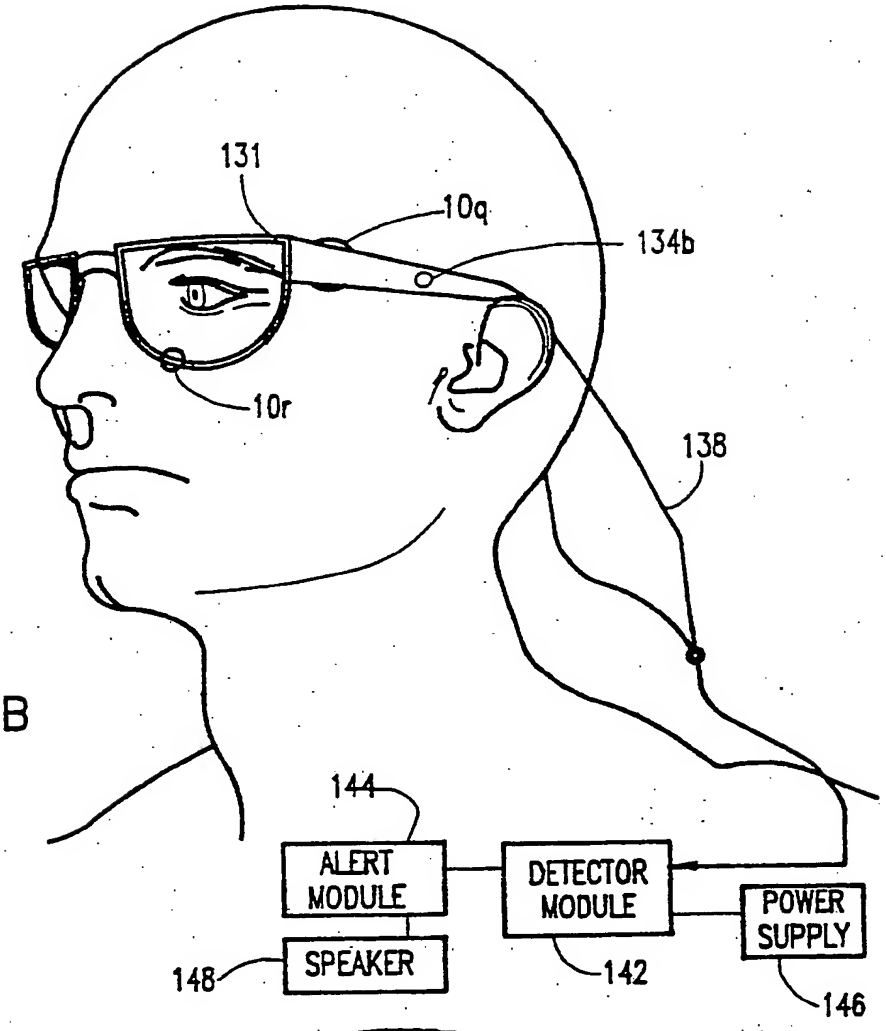

148
138
10t
131
10q
130
SPEAKER
144
ALERT MODULE
142
DETECTOR MODULE
140
POWER SUPPLY
146
10s
132
10r

FIG.9A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10q
134b
10r
138
144
ALERT MODULE
DETECTOR MODULE
POWER SUPPLY
148
SPEAKER
142
146

FIG.9B

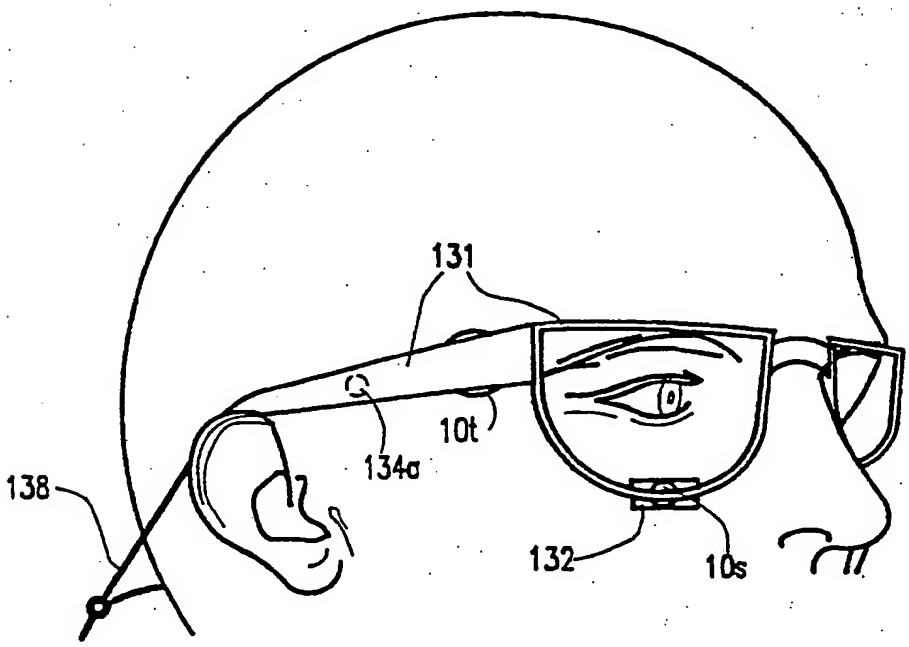

131
10t
134a
138
132
10s

FIG.9C

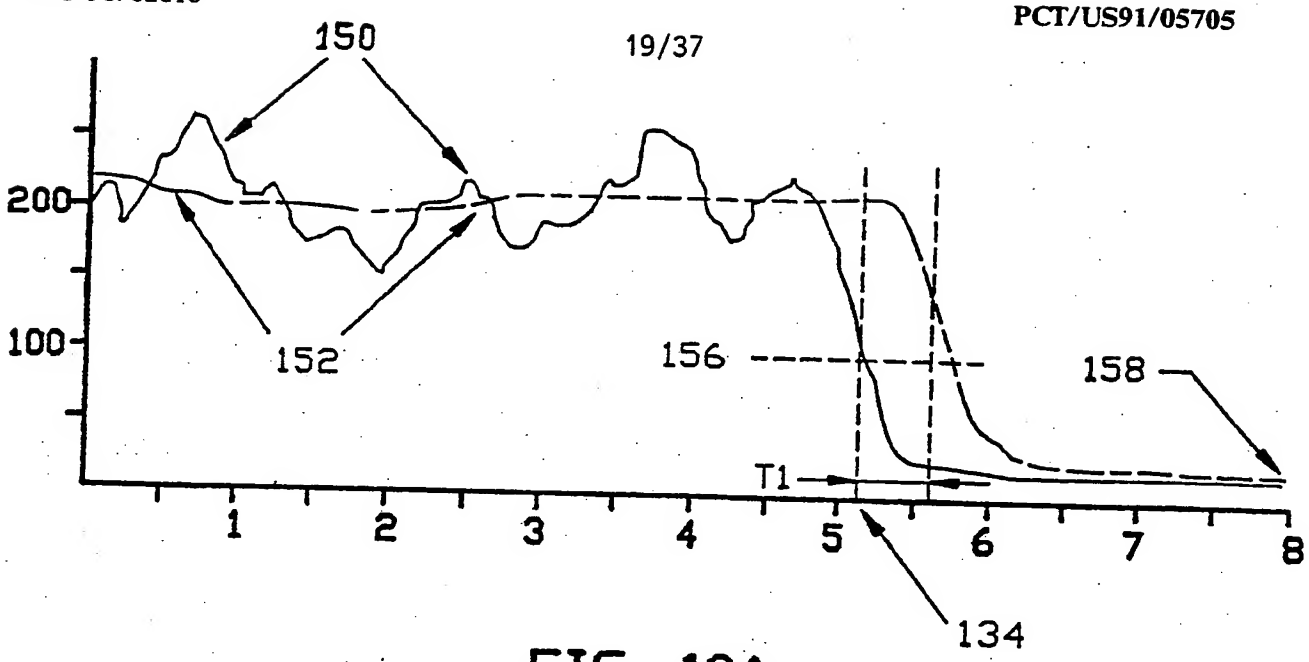


FIG. 10A

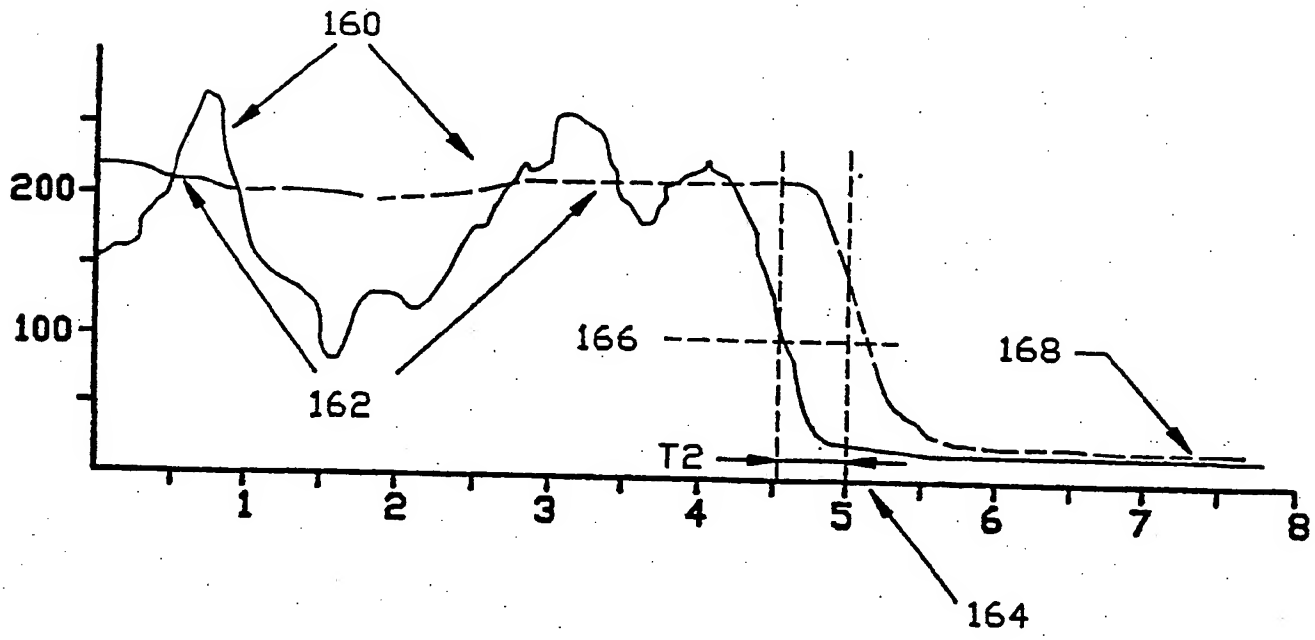


FIG. 10B

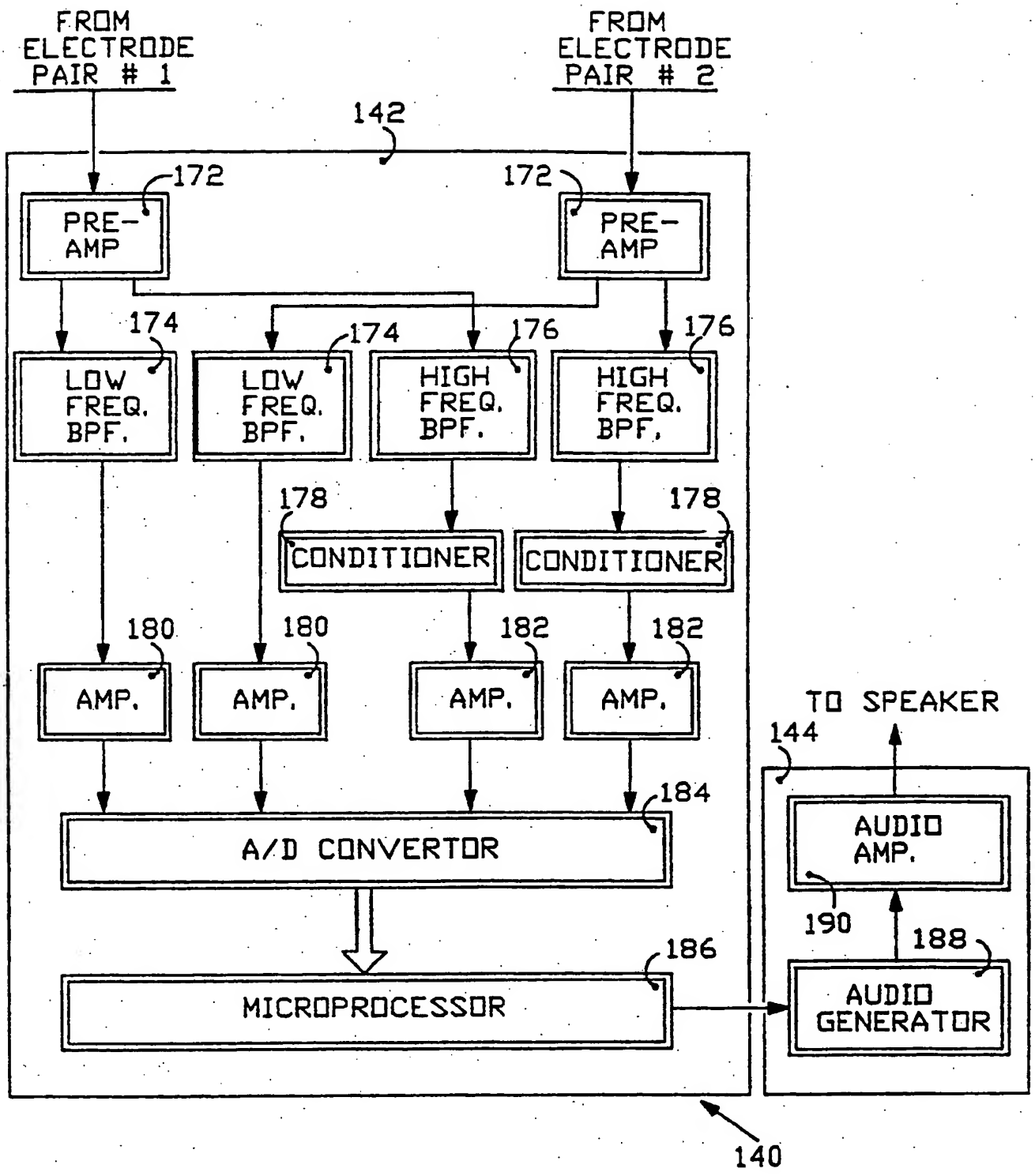

FROM ELECTRODE PAIR # 1
FROM ELECTRODE PAIR # 2
142
172
172
PRE-AMP
PRE-AMP
174
174
176
176
LOW FREQ. BPF.
LOW FREQ. BPF.
HIGH FREQ. BPF.
HIGH FREQ. BPF.
178
178
CONDITIONER
CONDITIONER
180
180
182
182
AMP.
AMP.
AMP.
AMP.
TO SPEAKER
144
184
A/D CONVERTOR
AUDIO AMP.
190
188
186
MICROPROCESSOR
AUDIO GENERATOR
140

FIG. 11

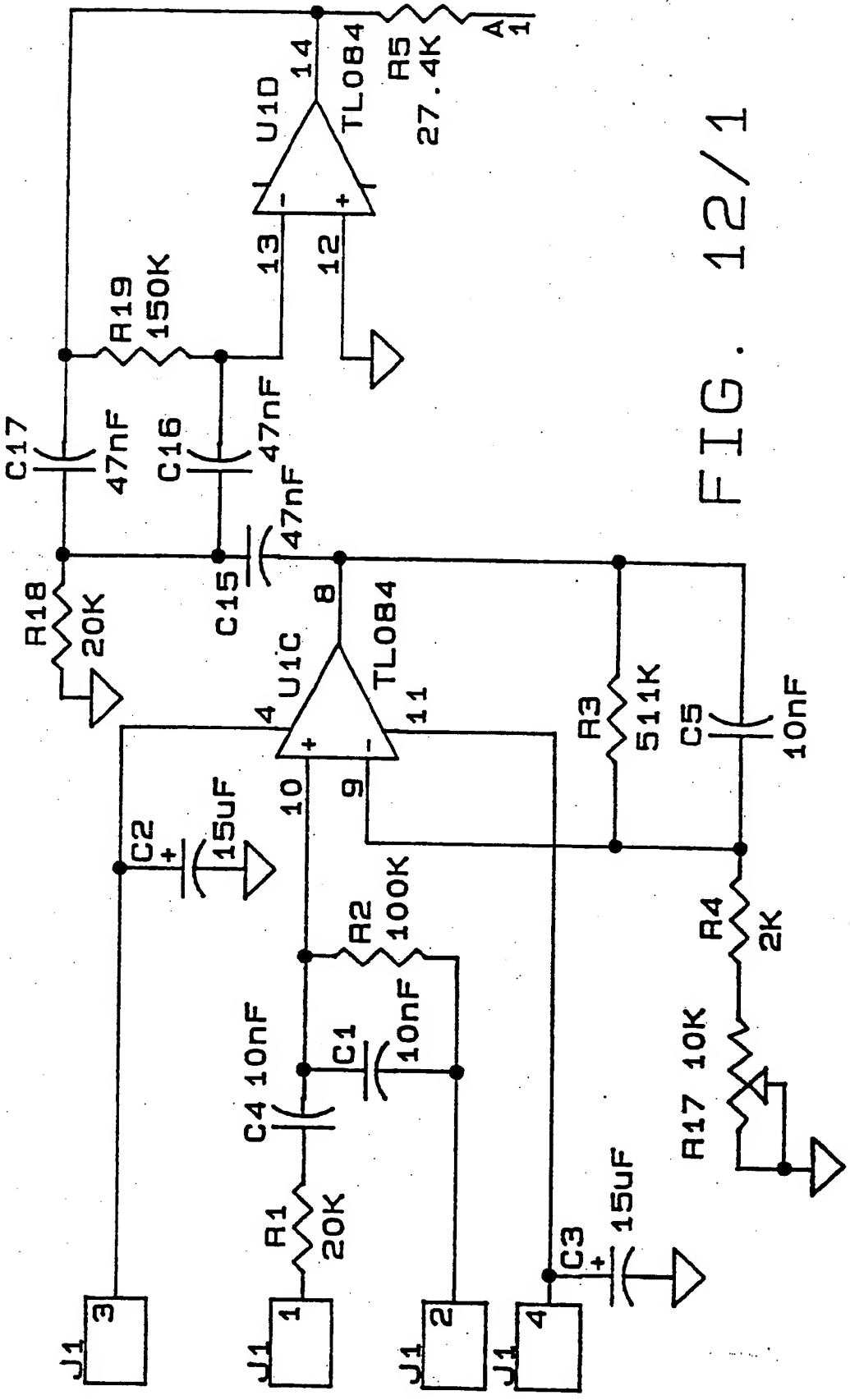

U1D
TL084
14
13
12
R5
27.4K
A
1
R19
150K
C17
47nF
C16
47nF
C15
47nF
R18
20K
U1C
TL084
8
4
11
10
9
R3
511K
C5
10nF
C2
15uF
R2
100K
R4
2K
C4 10nF
C1
10nF
R17 10K
R1
20K
C3
15uF
J1
3
J1
1
J1
2
J1
4

FIG. 12/1

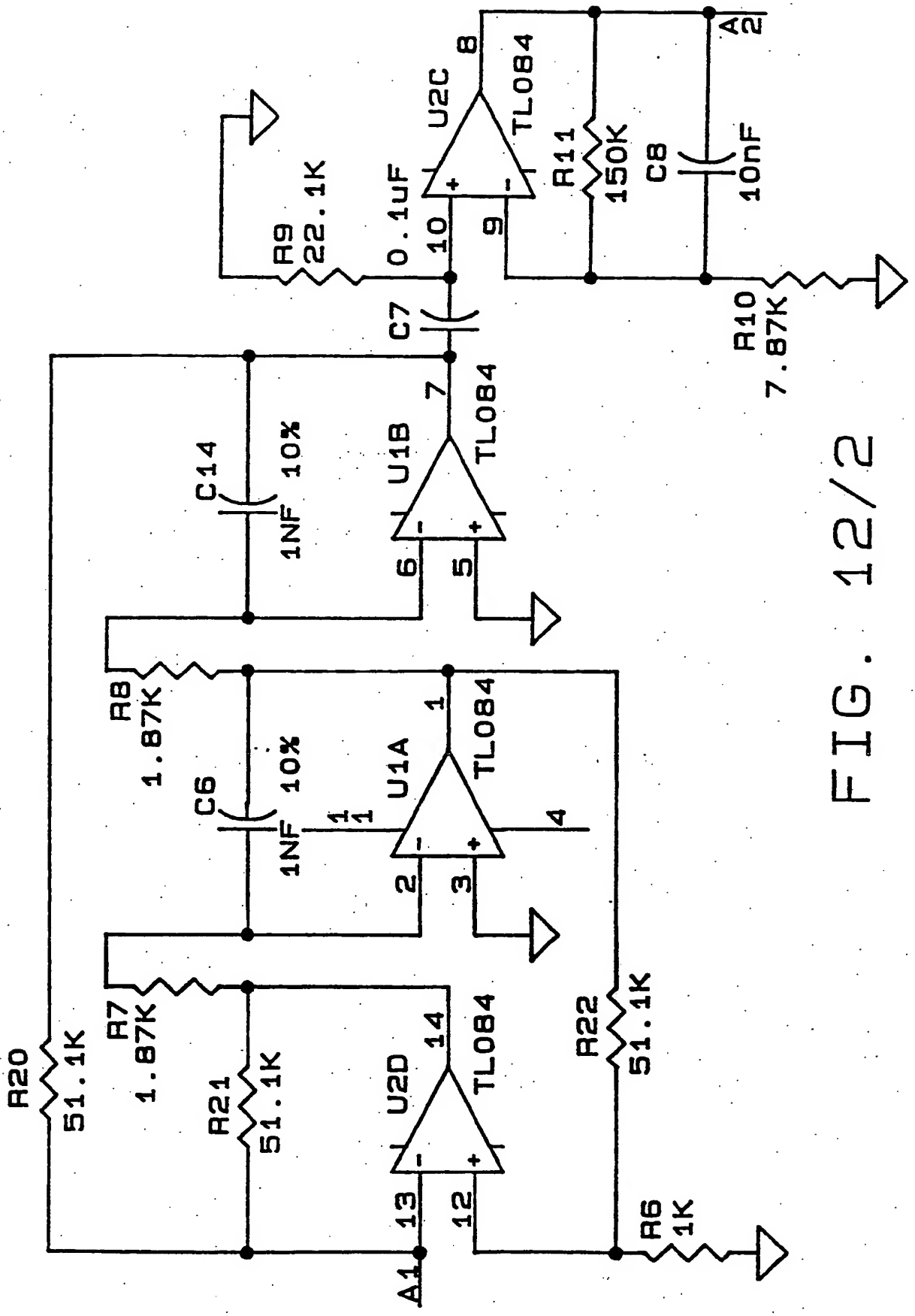

A2
8
U2C
TL084
R11
150K
C8
10nF
R9
22.1K
0.1uF
10
9
C7
R10
7.87K
7
U1B
TL084
C14
10%
1NF
6
5
R8
1.87K
1
U1A
TL084
C6
10%
1NF
1
1
4
2
3
R7
1.87K
R20
51.1K
R21
51.1K
14
U2D
TL084
R22
51.1K
13
12
A1
R6
1K

FIG. 12/2

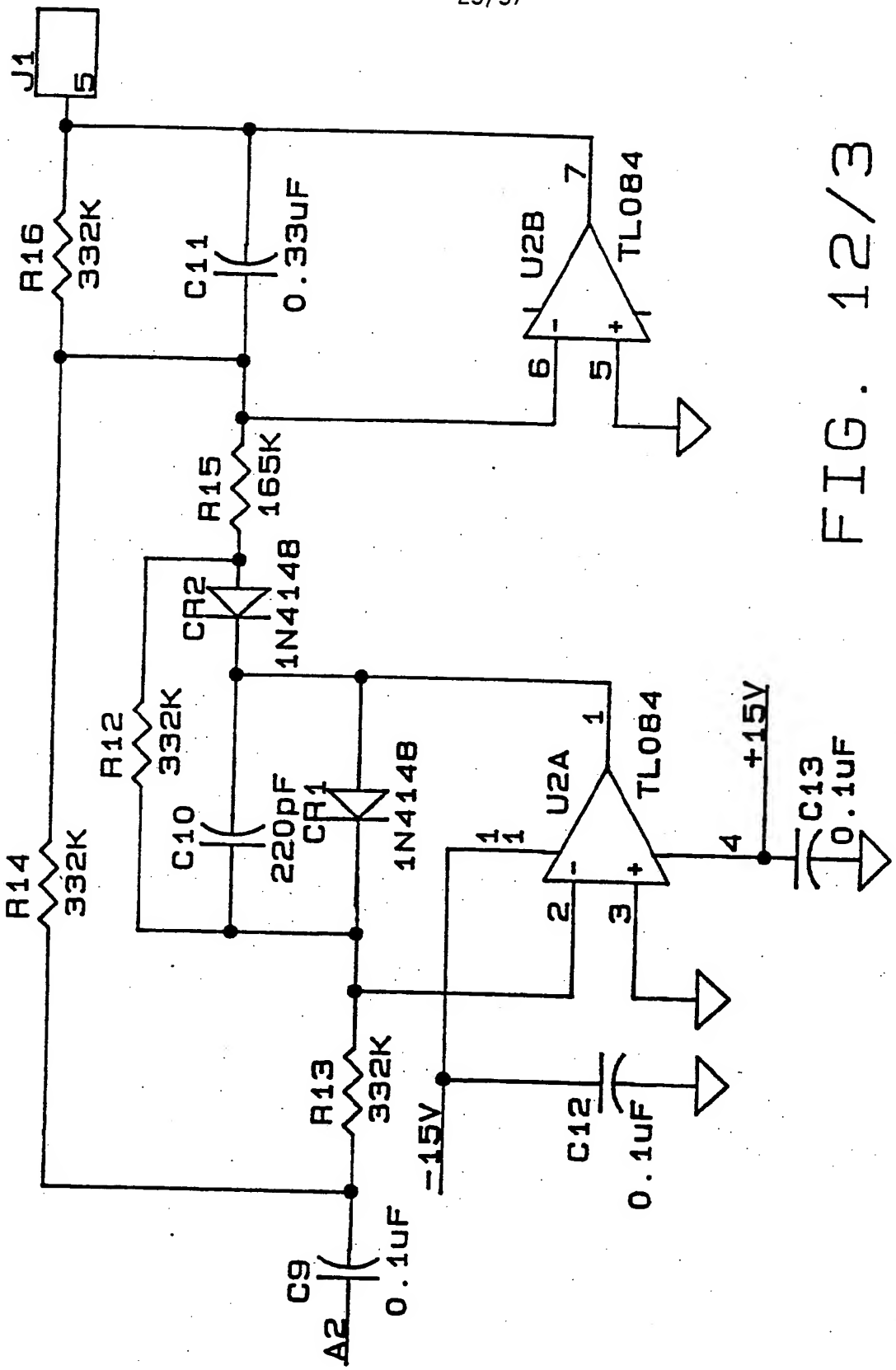

J1
5
R16
332K
C11
0.33uF
U2B
TL084
7
6
5
R15
165K
CR2
1N4148
R12
332K
C10
220pF
CR1
1N4148
U2A
TL084
1
2
3
4
+15V
C13
0.1uF
R14
332K
R13
332K
-15V
C12
0.1uF
C9
0.1uF
A2

FIG. 12/3

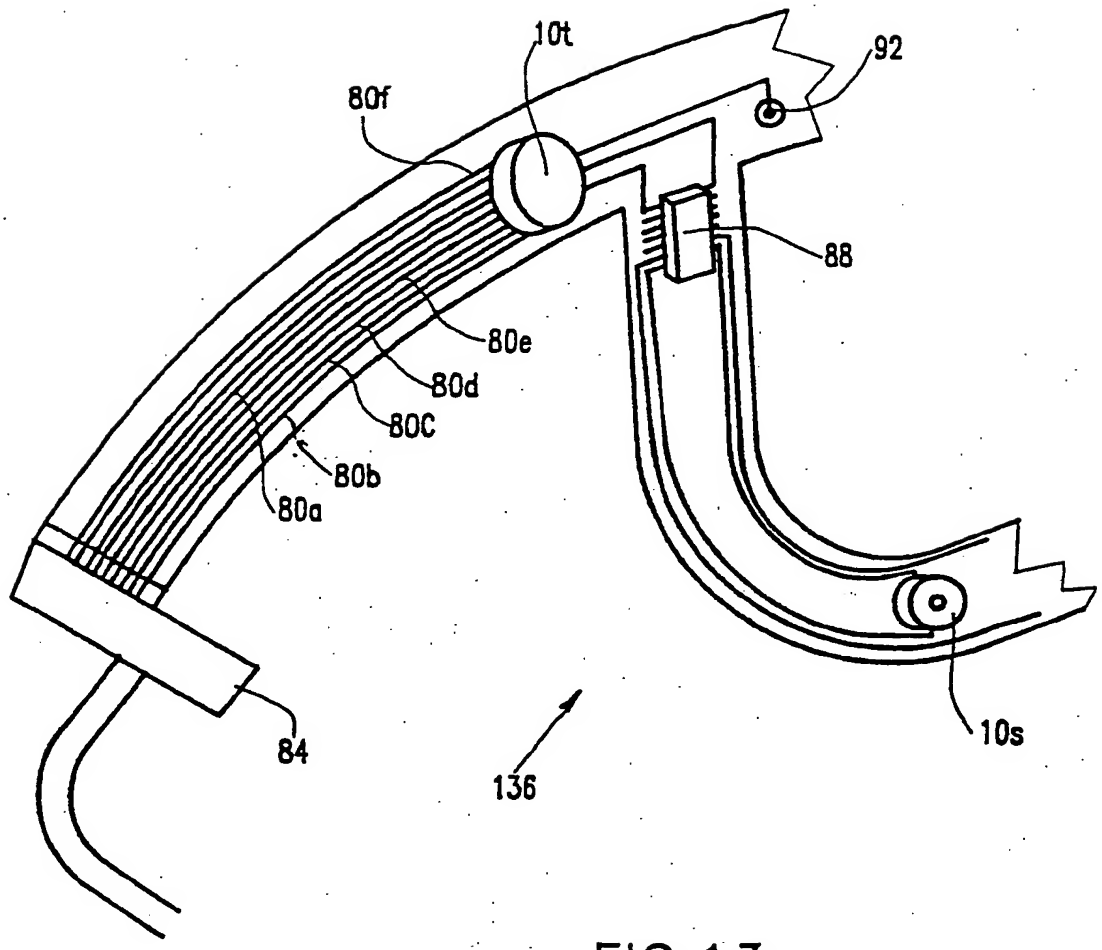


FIG.13

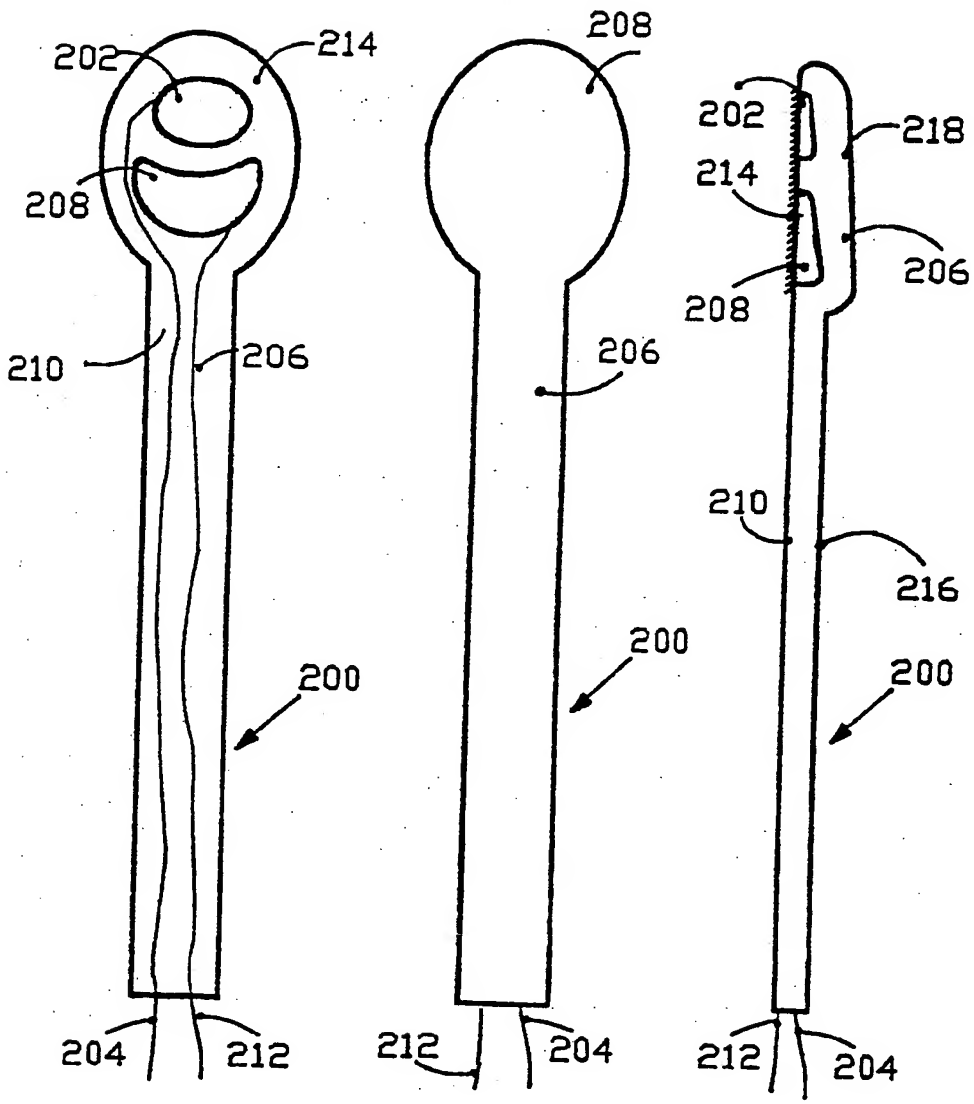


FIG. 14A FIG. 14B FIG. 14C

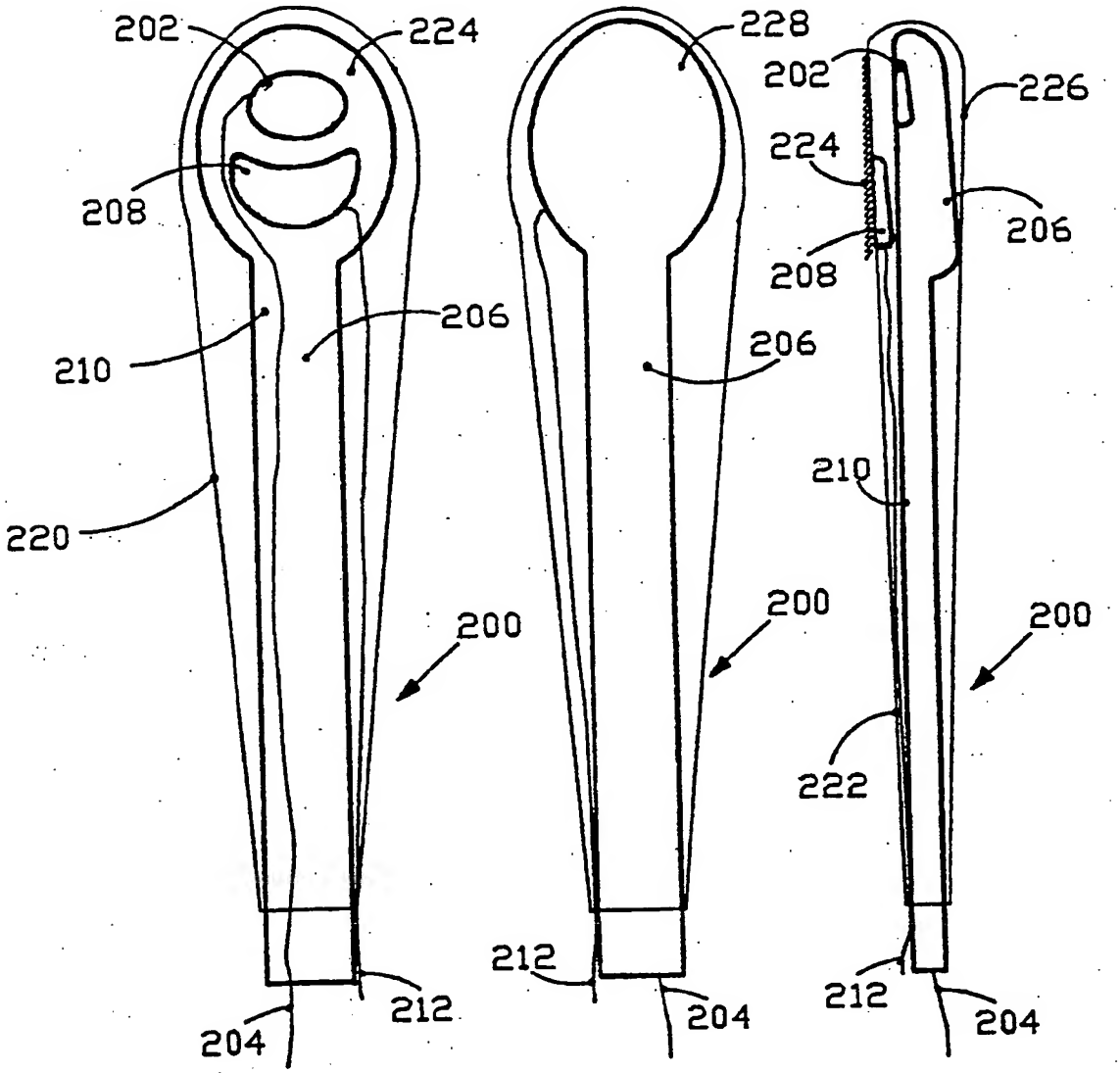


FIG. 15A FIG. 15B FIG. 15C

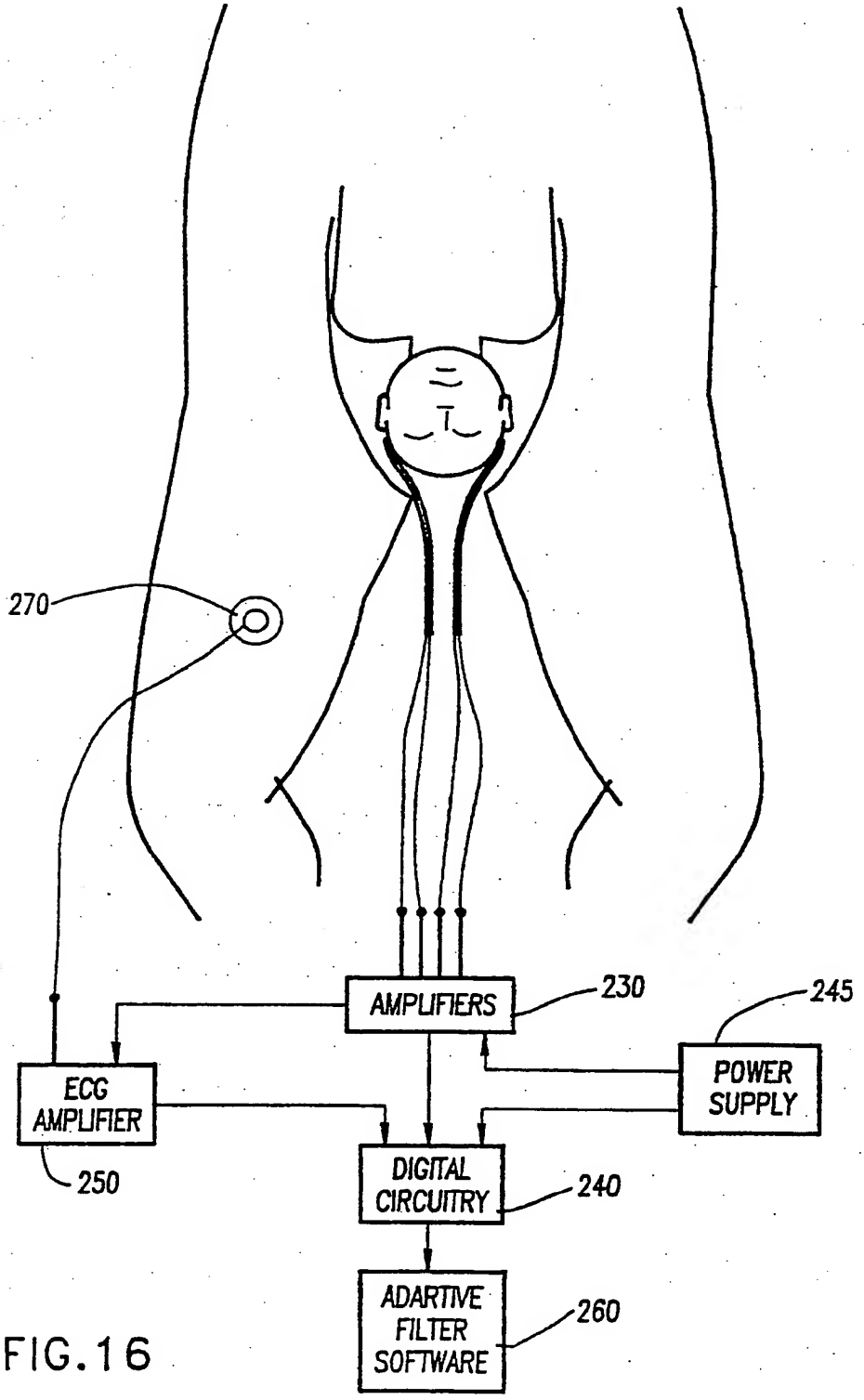

270
AMPLIFIERS
230
245
POWER SUPPLY
ECG AMPLIFIER
250
DIGITAL CIRCUITRY
240
ADARTIVE FILTER SOFTWARE
260

FIG.16

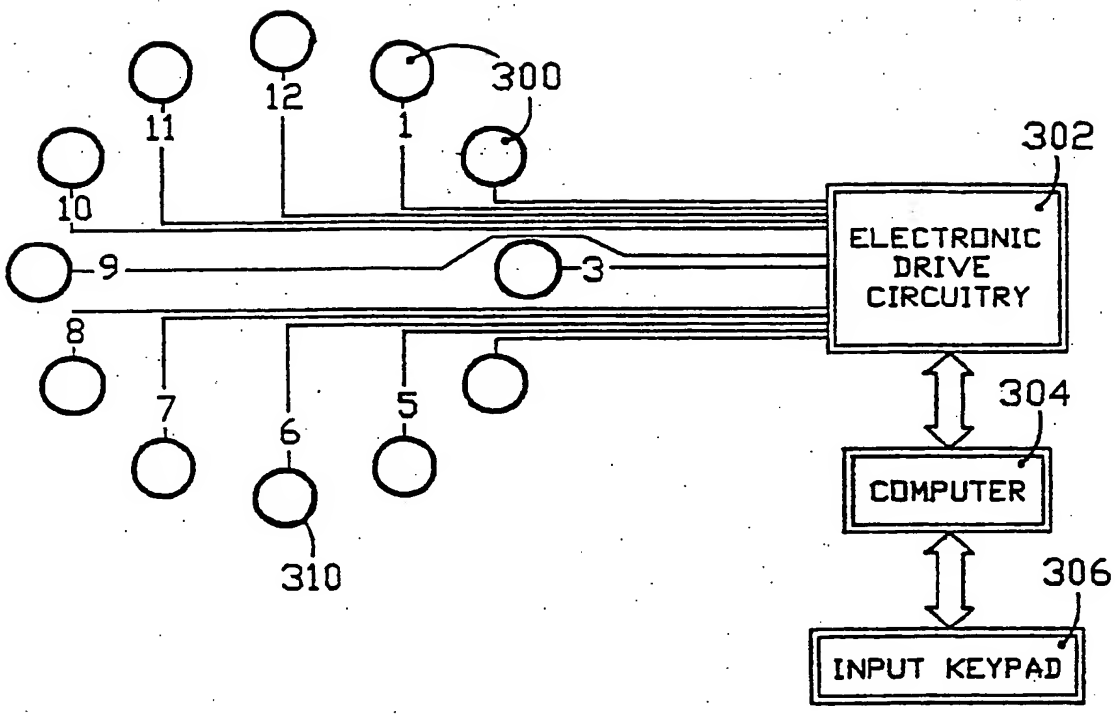

300
12
11
1
10
302
9
3
8
7
6
5
310
ELECTRONIC DRIVE CIRCUITRY
304
COMPUTER
306
INPUT KEYPAD

FIG. 17

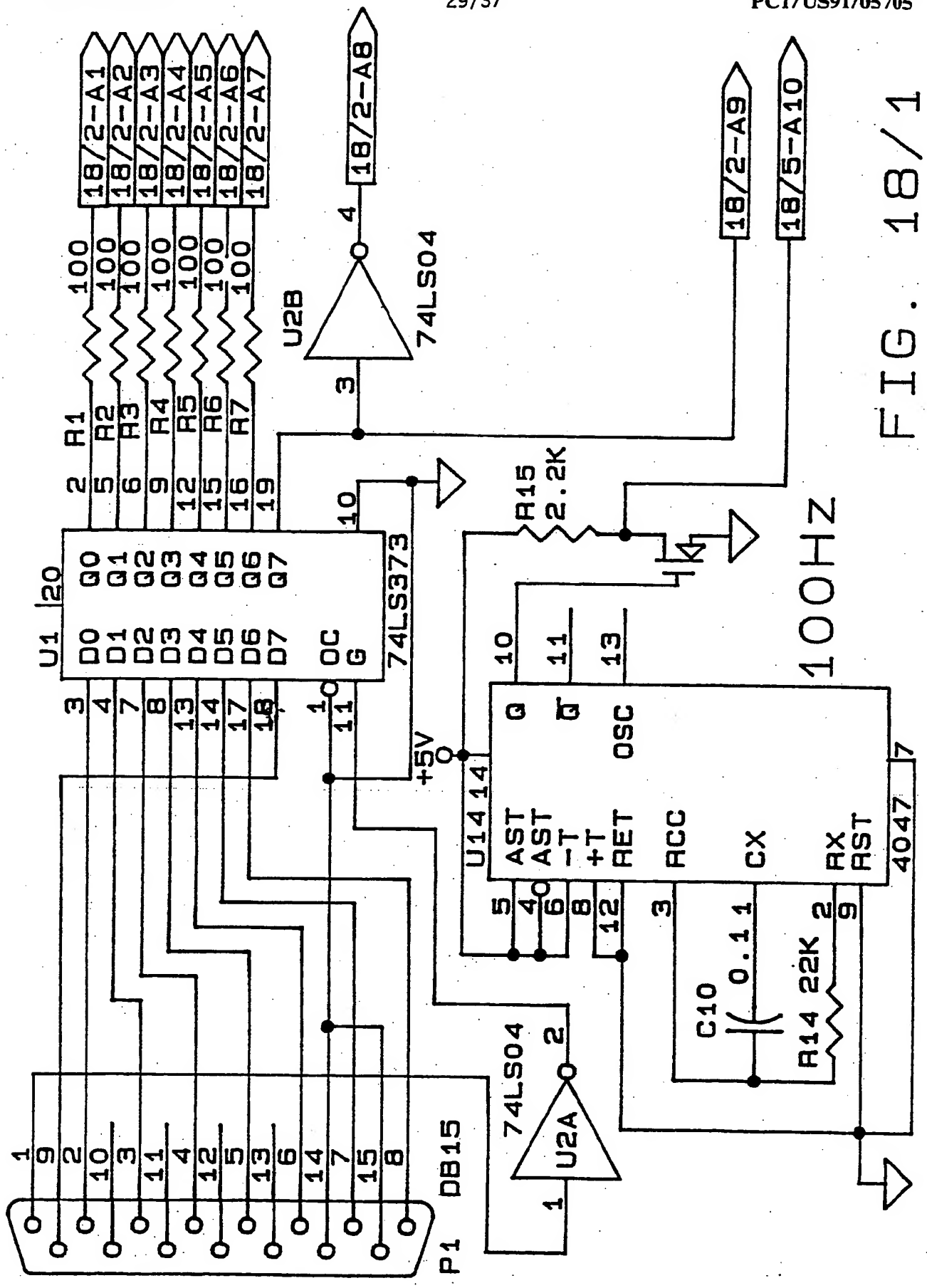

18/2-A1
18/2-A2
18/2-A3
18/2-A4
18/2-A5
18/2-A6
18/2-A7
18/2-A8
18/2-A9
18/5-A10
100
R1
R2
R3
R4
R5
R6
R7
U2B
74LS04
U1
74LS373
D0 D1 D2 D3 D4 D5 D6 D7
OC
G
R15 2.2K
100HZ
U14
4047
AST
-T
+T
RET
RCC
CX
RX
RST
OSC
C10 0.11
R14 22K
+5V
U2A
P1 DB15

FIG. 18/1

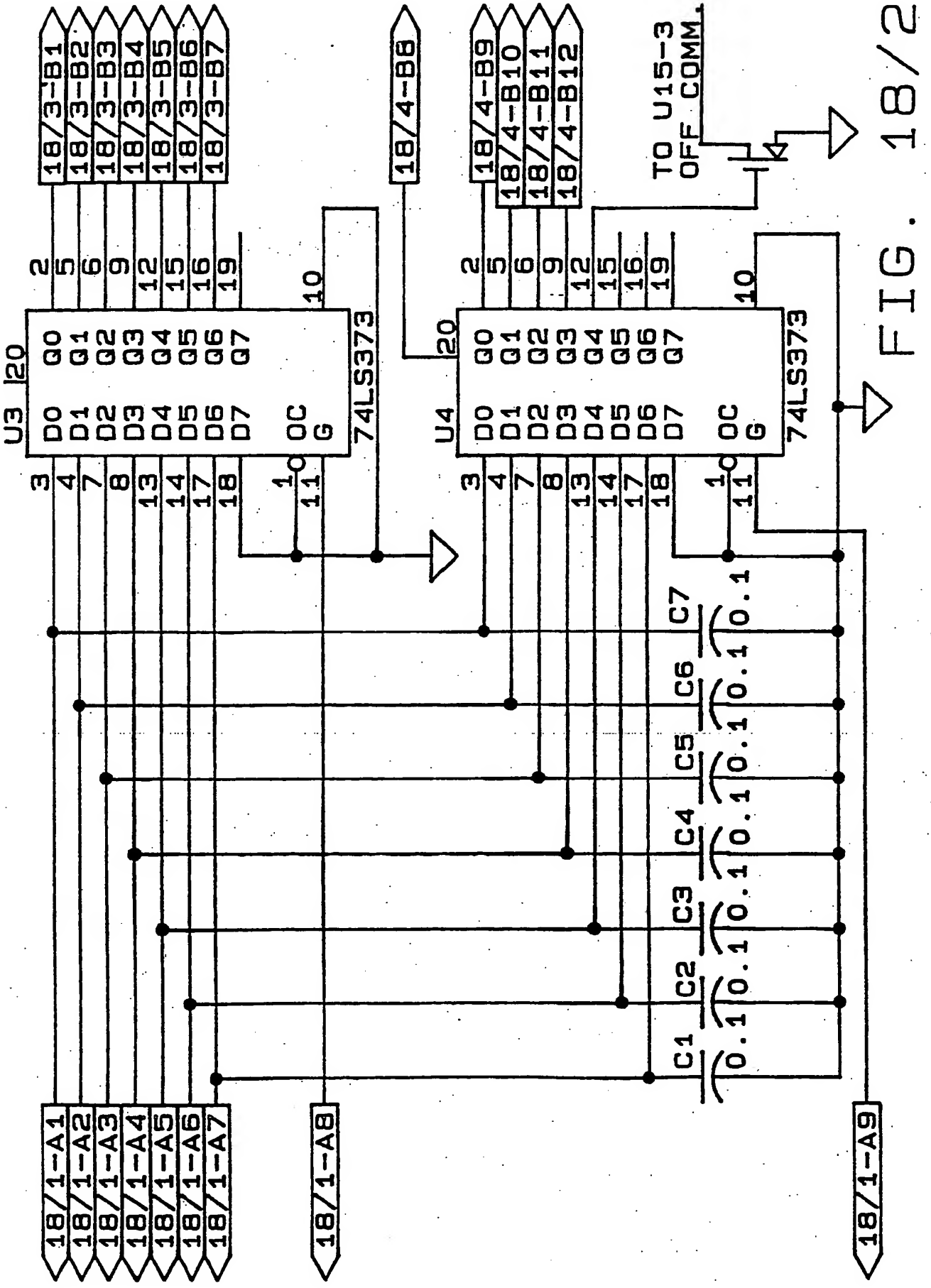

18/3-B1
18/3-B2
18/3-B3
18/3-B4
18/3-B5
18/3-B6
18/3-B7
18/4-B8
18/4-B9
18/4-B10
18/4-B11
18/4-B12
TO U15-3
OFF COMM.
U3
U4
74LS373
D0 D1 D2 D3 D4 D5 D6 D7
Q0 Q1 Q2 Q3 Q4 Q5 Q6 Q7
OC
G
C1
C2
C3
C4
C5
C6
C7
0.1
18/1-A1
18/1-A2
18/1-A3
18/1-A4
18/1-A5
18/1-A6
18/1-A7
18/1-A8
18/1-A9

FIG. 18/2

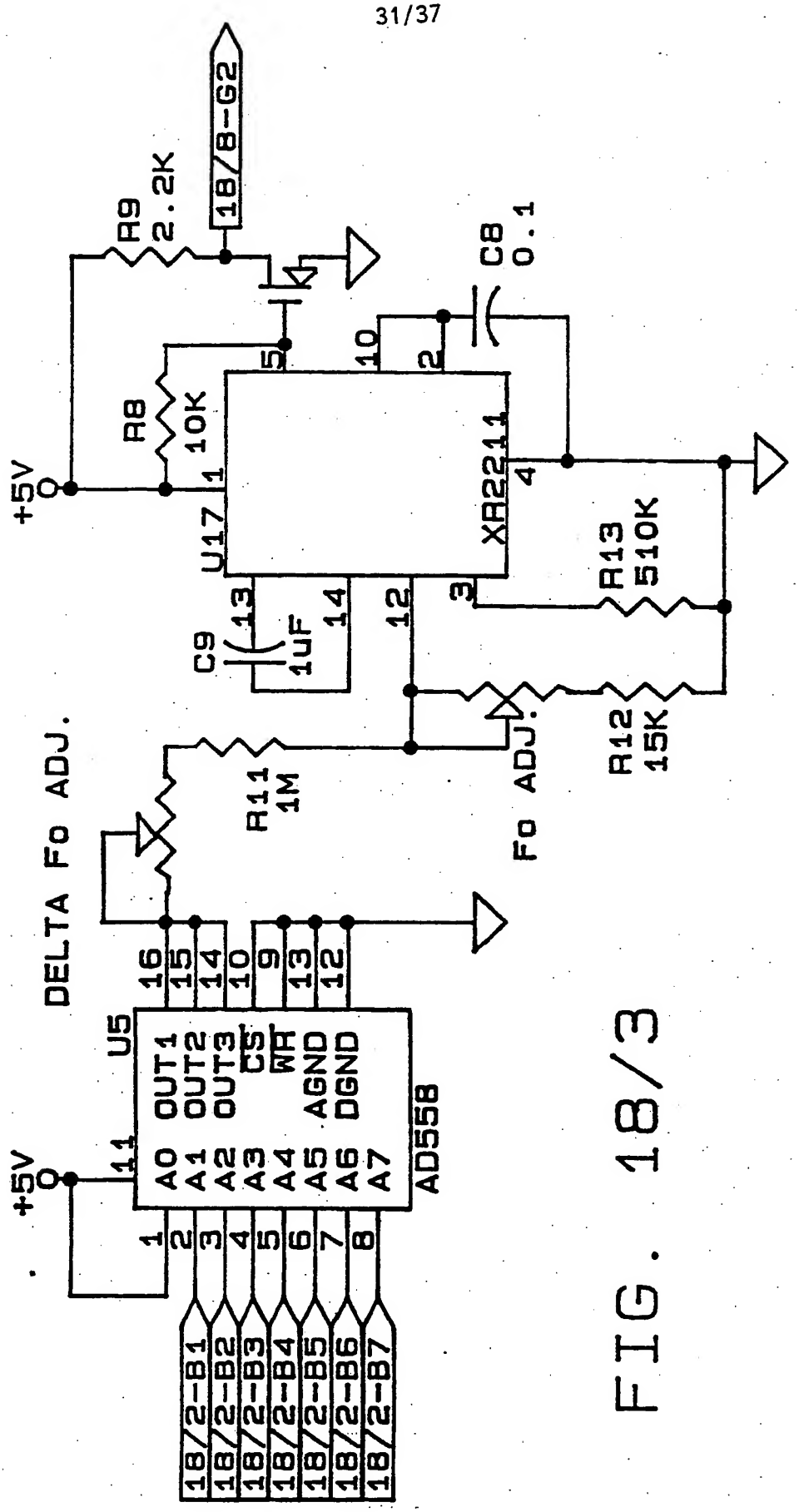

18/8-G2
R9
2.2K
C8
0.1
R8
10K
+5V
U17
XR2211
R13
510K
C9
1UF
R12
15K
R11
1M
DELTA Fo ADJ.
Fo ADJ.
U5
OUT1
OUT2
OUT3
CS
WR
AGND
DGND
A0
A1
A2
A3
A4
A5
A6
A7
AD558
18/2-B1
18/2-B2
18/2-B3
18/2-B4
18/2-B5
18/2-B6
18/2-B7

FIG. 18/3

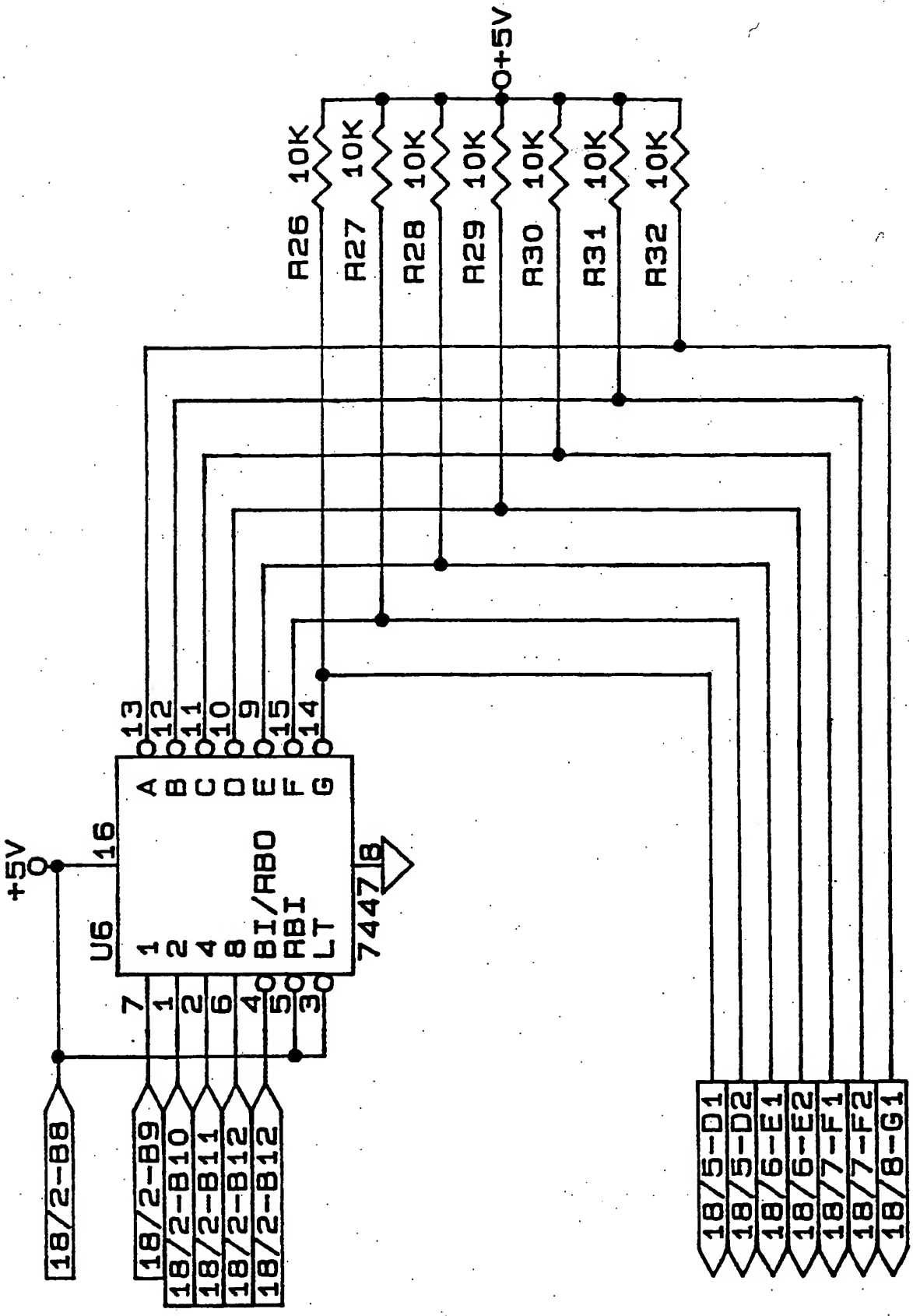

+5V
R26 10K
R27 10K
R28 10K
R29 10K
R30 10K
R31 10K
R32 10K
13 12 11 10 9 15 14
A B C D E F G
16
+5V
U6
1 2 4 8 BI/RBO RBI LT
7447
8
7 1 2 6 4 5 3
18/2-B8
18/2-B9
18/2-B10
18/2-B11
18/2-B12
18/2-B12
18/5-D1
18/5-D2
18/6-E1
18/6-E2
18/7-F1
18/7-F2
18/8-G1

FIG. 18/4

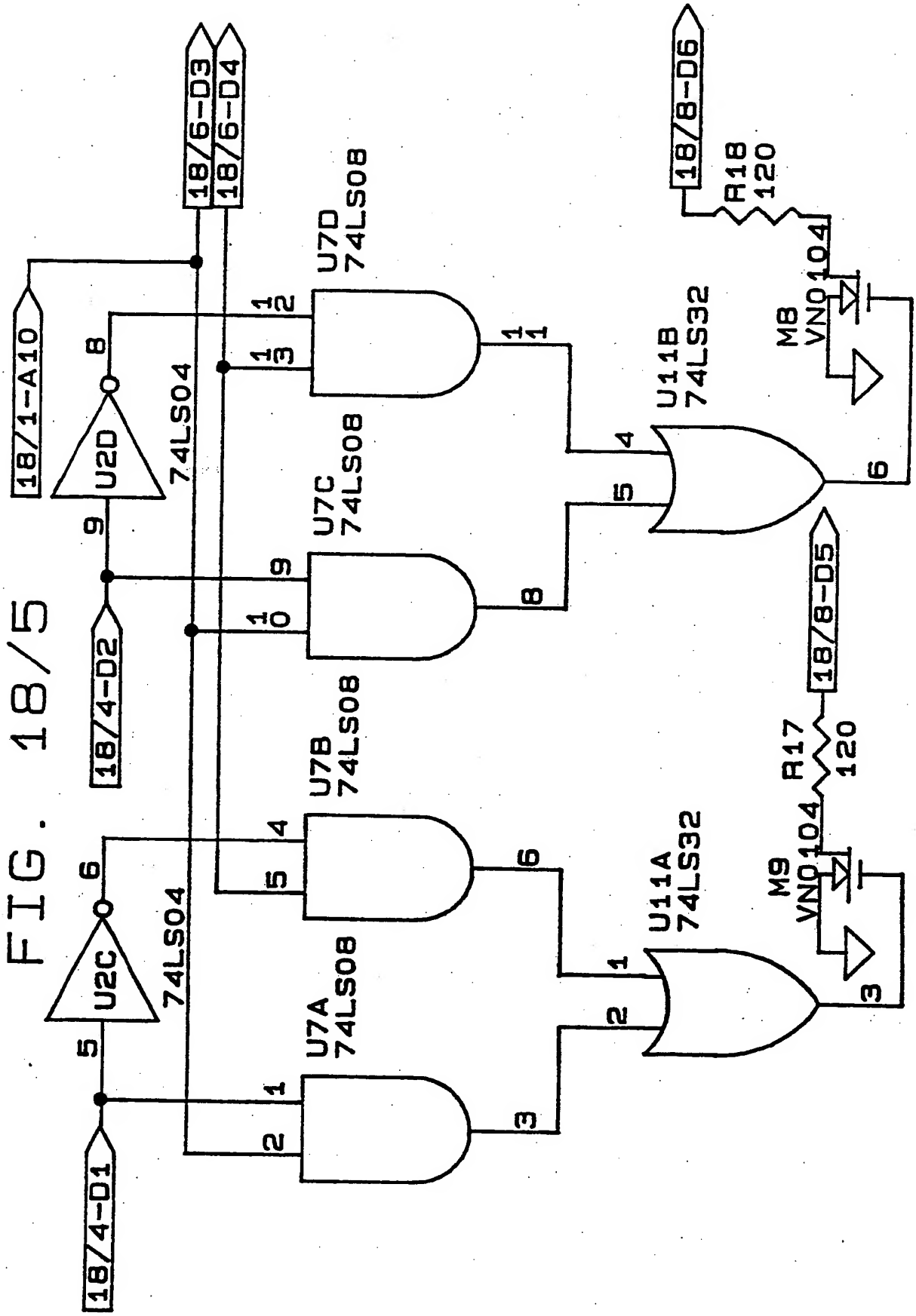
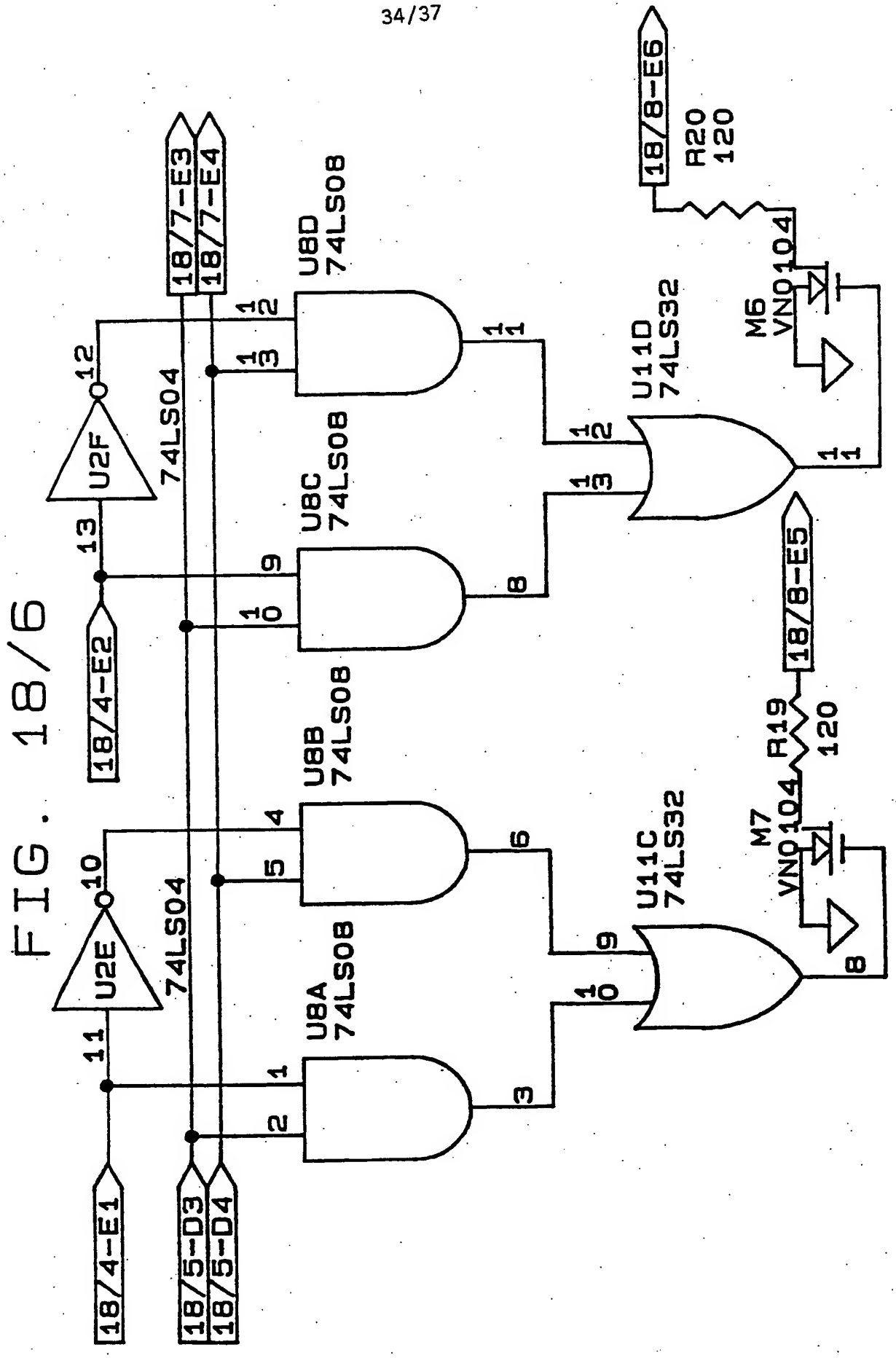

18/6-D3
18/6-D4
18/8-D6
R18
120
M8
VN0104
18/1-A10
U2D
74LS04
U7D
74LS08
U11B
74LS32
U7C
74LS08
18/4-D2
18/8-D5
R17
120
M9
VN0104
U7B
74LS08
U2C
74LS04
U11A
74LS32
U7A
74LS08
18/4-D1

FIG. 18/5

FIG. 18/6


18/4-E1
18/5-D3
18/5-D4
18/4-E2
18/7-E3
18/7-E4
18/8-E5
18/8-E6
U2E
U2F
74LS04
U8A
U8B
U8C
U8D
74LS08
U11C
U11D
74LS32
R19
R20
120
M6
M7
VN0104

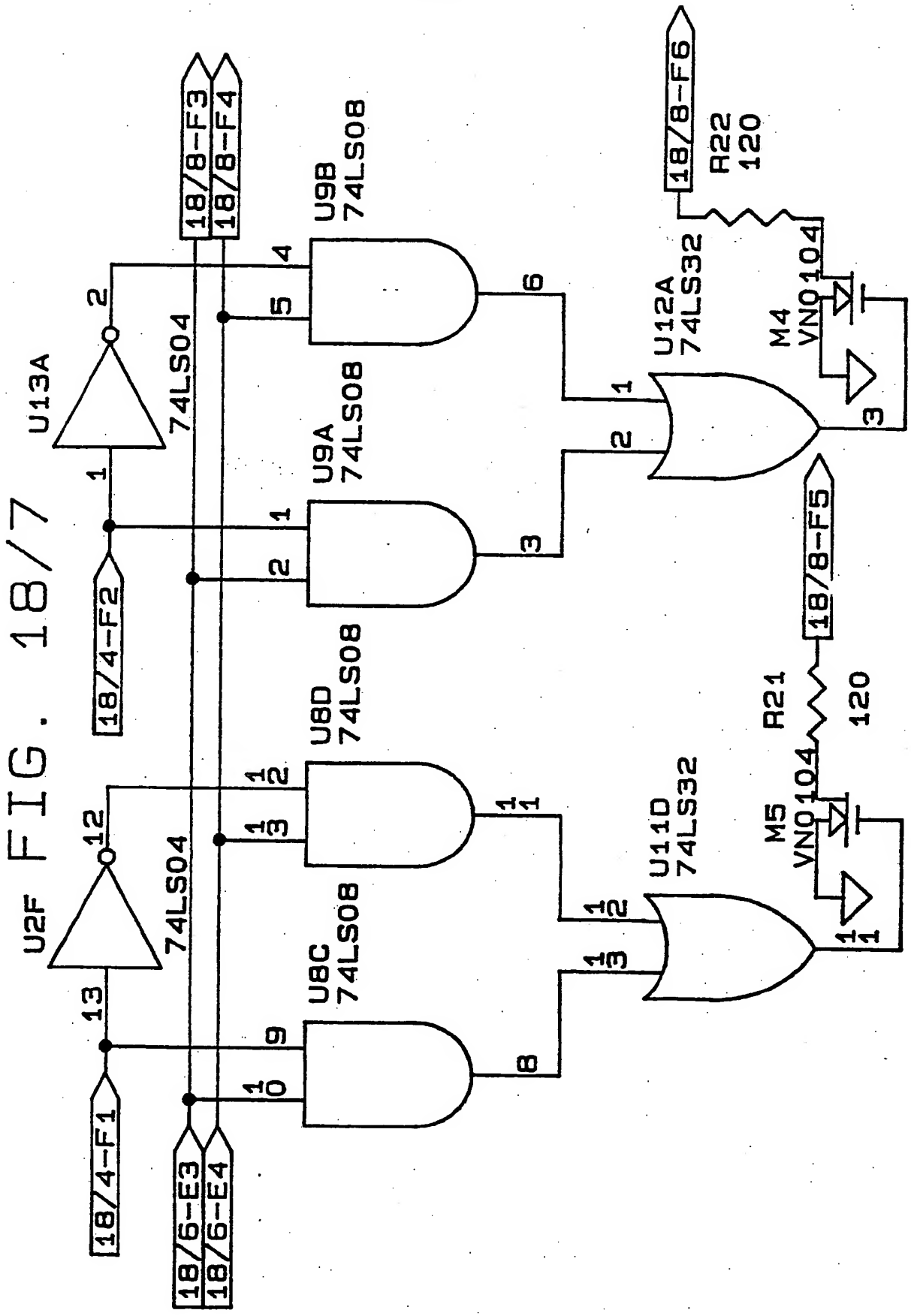

18/8-F3
18/8-F4
18/8-F6
R22
120
U9B
74LS08
U12A
74LS32
M4
VN0104
U13A
74LS04
U9A
74LS08
18/8-F5
18/4-F2
U8D
74LS08
R21
120
U2F
74LS04
U8C
74LS08
U11D
74LS32
M5
VN0104
18/4-F1
18/6-E3
18/6-E4

FIG. 18/7

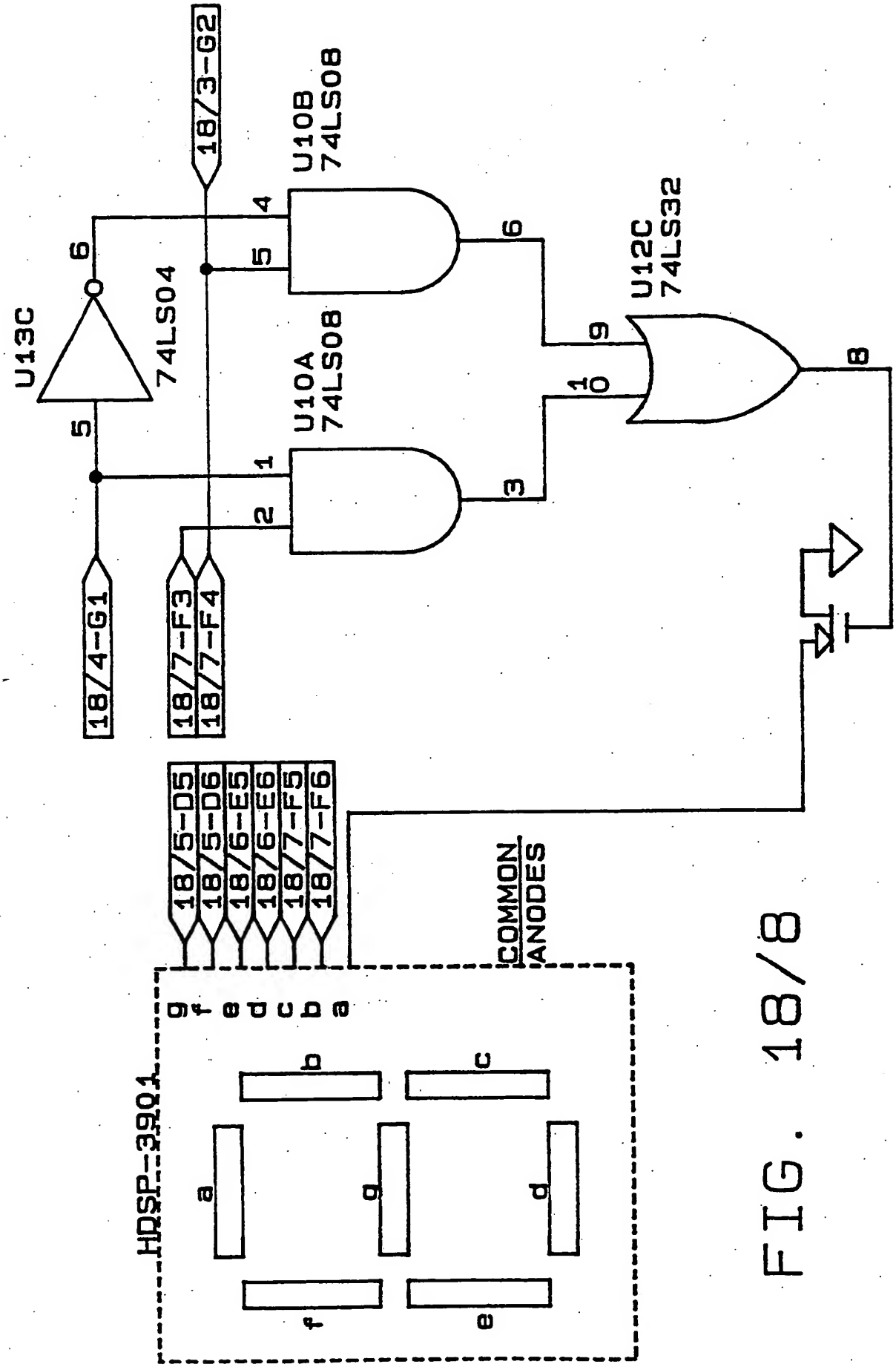

18/3-G2
U10B
74LS08
U12C
74LS32
U13C
74LS04
U10A
74LS08
18/4-G1
18/7-F3
18/7-F4
18/5-D5
18/5-D6
18/6-E5
18/6-E6
18/7-F5
18/7-F6
COMMON
ANODES
HDSP-3901
g f e d c b a

FIG. 18/8

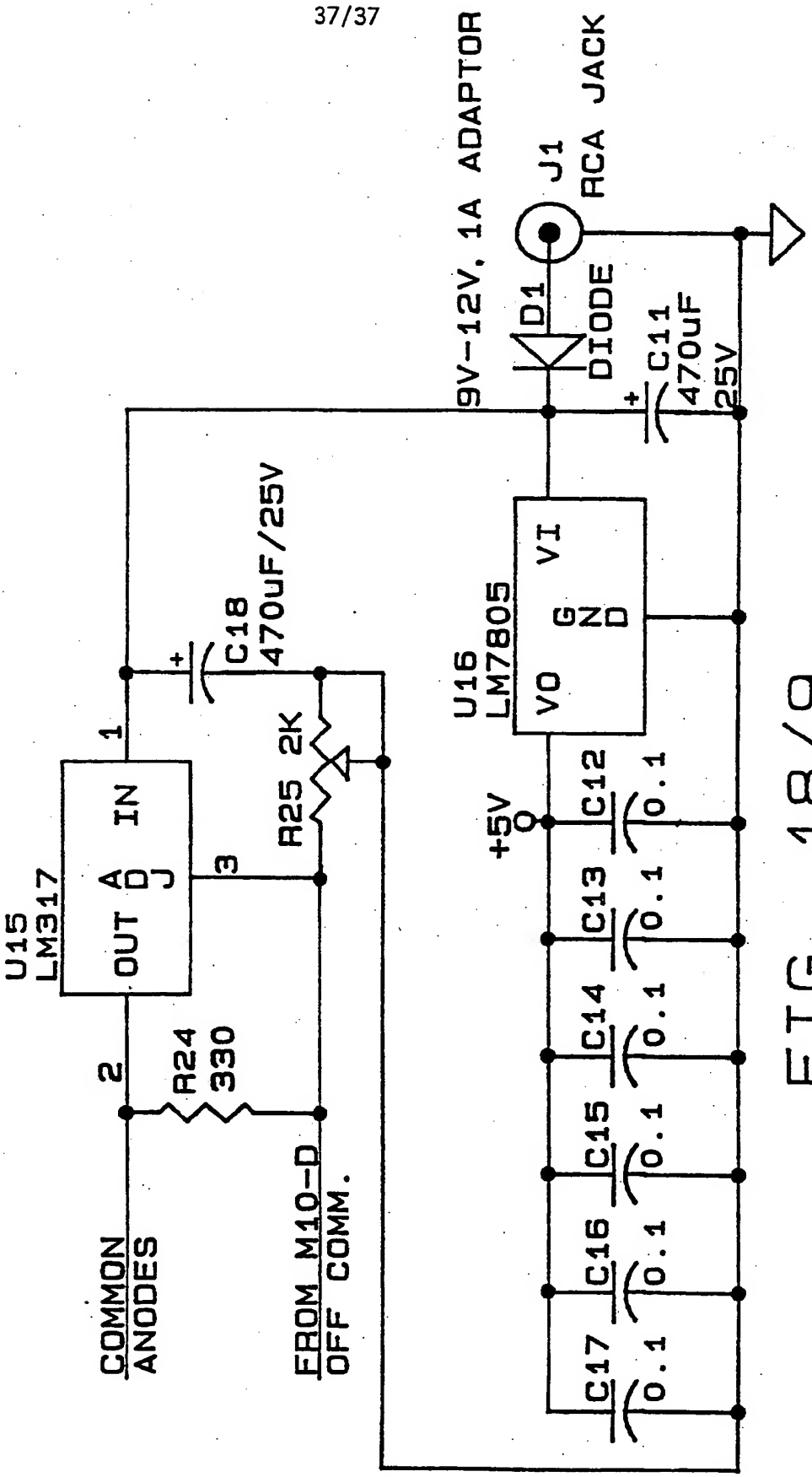

9V-12V, 1A ADAPTOR
J1
RCA JACK
D1
DIODE
C11
470uF
25V
C18
470uF/25V
U16
LM7805
VI
GND
VO
U15
LM317
IN
ADJ
OUT
R25 2K
R24
330
1
2
3
+5V
C12
C13
C14
C15
C16
C17
0.1
COMMON
ANODES
FROM M10-D
OFF COMM.

FIG. 18/9

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/05705

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5) A61B 5/04
U.S. CL. 128/639; 128/644

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	128/639.641,644

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US,A, 3,744,482 (KAUFMAN) 10JULY 1973, See column 2, line 49 column 3, line 13	11
A	US,A, 4,078,553 (DUROUX) 14 MARCH 1978, See entire document	1
Y	US,A, 4,425,921 (FUJISAKI) 17 JANUARY 1984, See entire document	13
Y	US,A, 4,697,598 (BERNARD) 06 OCTOBER 1987, See entire See entire document	37-47
X/Y	US,A, 4,763,660 (KROLL) 16 AUGUST 1988 See entire document	1-10,12/13
Y	DE,A, 2,633,439 (SCHULER) 26 JANUSRY 1978 See entire document	37-47
X/Y	WO,A, 0,003,672 (TROESCH) 29 JUNE 1989 See entire document	1/11

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
04 NOVEMBER 1991	04 DEC 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	for LEE S. COHEN — NGUYEN NGOC-HO INTERNATIONAL DIVISION